# PFNDAI Bulletin (July 2012)

# Protein Foods and Nutrition Development Association of India

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# Editorial

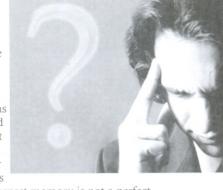
**Memory** is something that has always created problems for everyone sometime or the other. Either it is the loss of memory on your part or indelible memory about you in someone else's mind that has given trouble to most of us. This is more so as the age advances and you start forgetting some things either happily or unwillingly.

There have been several ayurvedic herbs that have the ability of memory enhancement like Brahmi (Bacopa), Ashwagandha (Withania), and Mulethi (Glycyrrhiza) as well as Ginko and Gotu kola are used for memory enhancement. There are vitamins, minerals and omega 3 fatty acids that have been recommended for sharper memory. Some of these have also been reported to delay some old-age diseases like Alzheimer's disease. Many products have appeared in the market claiming to enhance memory and the market for such supplements is growing as people do not want to forget things.

It may look as a simple problem of memory loss or we may refer to it as forgetfulness. However, Harvard Medical School lists seven normal memory problems. Transience is the tendency to forget facts or events over time unless this memory is recalled. This is a beneficial aspect when the brain clears unused memory so that more useful memory can be stored. Absentmindedness is when one does not pay close enough attention. Everyone is quite familiar with this especially in meetings and classrooms when things are not very interesting and the mind wanders.

There are memory problems called misattribution where one remembers something accurately but with wrong context with

respect to time, place or person involved. This happens more when one ages. This is also very common. What is less known is suggestibility, which is when one learns about an occurrence and later starts believing that he or she was present at the occurrence. Another problem with memory is



called bias. Even the sharpest memory is not a perfect snapshot of reality and one's perceptions are filtered by personal biases. These affect the way memory is stored in brain and when recalled, some part that is filtered out is not recalled.

There is one more problem of memory and that is persistence. Most of us worry about forgetting things but in some cases people are bothered by memories that they wish to forget. These are mostly traumatic events, negative feelings and fears.

Thus memory is not something like a computer chip and there are different types of memory problems. One wonders then which type of memories are improved by these various memory enhancing substances. Do they all work similarly or synergistically? There may be many interesting things that could be studied by research and need to be established while we consume all these supplements that light up a bulb in our minds.

With season's greetings!

Prof. Jagadish S. Pai, Executive Director executivedirector@pfndai.org

# 10-11 January 2013 1st International Conference on Innovations in Food Processing, Value Chain Management & Food Safety

NIFTEM (National Inst of Food Tech Entrepreneurship & Management NIFTEM Campus, Sonepat, Haryana (Near Delhi)

Tel: 0130-2281000/2219759-64, Email: ifpvs2013@gmail.com
Web: www.niftem.ac.in

#### 23-24 February 2013 International Conference on Digestive Disorders

Tirupati, Andhra Pradesh Indian Assn. for Parenteral & Enteral Nutrition Tel: 080-41108677 Cell: 99867 95754 E: iapenmeet@gmail.com W:

www.iapen.co.in

#### 25-28 February 2013 Gulfood

Dubai World Trade Centre Web: www.gulfood.com

#### 6-7 March 2013 Nutracon

Anaheim, CA, USA New Hope Natural Media Tel: +1-866-458-4935 E: conferences@newhope.com W: www.nutraconference.com

#### 14-16 March 2013 India International Dairy Expo 2013

Bombay Exhibition Centre, Mumbai Indian Dairy Assn. &Koelnmesse Tel: 022-28715205 E: s.rajawat@koelnmesse-india.com

# **Coming Events**

#### 14-16 May 2013 Vitafoods Europe

Geneva, Switzerland Tel: 44-20-701-76482 E: daria.smith@informa.com W: www.vitafoods.eu.com

#### 13-17 July 2013 Institute of Food Technologists (IFT)

Annual Meeting & Food Expo Chicago, USA Tel: +1.312.782.8424 E: info@ift.org, W: www.am-fe.ift.org



#### Safety and Efficacy Assessment of Bioactive molecules / Functional foods / Nutraceuticals

#### Dr. B. Sesikeran, Director, National Institute of Nutrition, Hyderabad.

Food by definition is any substance that is consumed to provide nutritional support for the body. It is usually of plant or animal origin and contains essential nutrients such as carbohydrates fats, proteins, vitamins or minerals. The substance is ingested by an organism and assimilated by the organism cells in an effort to produce energy, maintain life or sustain growth . When we add the word functional as a prefix to food, it becomes 'Functional Food' which is food or food ingredient that gives an additional health benefit. Nutraceuticals on the other hand is food ingredient which is used like a pharmaceutical, it is product isolated and/or purified from foods that are generally sold in medicinal forms and is not usually associated with food.

Functional Foods, Nutraceuticals and Dietary supplements, all these have their activity due to the presence of bioactive molecules. These bioactive molecules are nothing but naturally occurring molecule from any living system like plant, animal, fungi, bacteria, algae, marine animal and they possess biological activity such as anti-proliferative, anti-infective, cholesterol reduction etc..

To give a much better understanding of the terminologies let us look at the example of Carrot. Carrot is a vegetable and consumed as food in our daily diet. Its consumption has benefit as it prevents blindness due to vitamin A deficiency. This additional health benefit puts it into the functional food category. The additional health benefit is due to the presence of beta carotene which is provitamin A, this is the bio active molecule whose presence provides the carrot its functional property. When only beta carotene is extracted from carrot and consumed in capsules form, its concentration increases and it is now called as nutraceuticals or food supplement.

There aremany such bioactive molecules whose health benefits are known since years and they are consumed for their known health benefits. To name a few are lutein- reduces risk of macular degeneration, Lycopene- reduces risk of prostate cancer, beta glucan and soluble fibre present in oats and psyllium are known to reduce risk of cardio vascular diseases, stanol ester- inhibit cholesterol absorption.

With the knowledge of health benefits that can be obtained by consumption of such food products, we also need to know what the Recommended Dietary Allowances (RDA) of these nutrients are. RDA is the recommended levels of nutrients to keep 95% of individuals healthy if consumed daily. Average Daily intake levels are calculated based on the population's average intake and it would be generally adequate for 50% of individuals. Safe Upper Limit (SUL) is the safest upper level which can be consumed daily by an individual throughout life and without any medical supervision.

The data of safety of the consumption has come from past, through traditional or published data wherein the observations have been made for years. People were consuming the product and their behavior and any physical changes wereobserved and at times recorded. Today with the advancements in technology, we are able to know the pathological effects in a shorter period of time and in much detailed manner. When any ingredient is discovered to have bioactivity, its physiochemical characterization is done and its pharmacokinetics is worked out. This shows the bioavailabilty of the ingredient, absorption, half life, accumulation in tissue, distribution, metabolism, excretion etc. The biological activity of any ingredient also takes into consideration its adverse effect levels that are LOAEL – Low adverse Effect Level / NOAEL- No adverse effect level, safe upper limits and also its effect in physiological states like pregnancy, lactation and on children.

To know the functional benefits of the compound, to identify and validate the predicted value and function of the compound, there are various markers identified. There are markers that relate to the level of consumption and bioavailability such as the plasma levels of the bioactive molecule. If the marker is related to risk of disease they are known as susceptible markers.

Everything that we consume has its risk and benefit; it is only the ratio of benefit to adverse effects that decides the safety of consumption. Snake venom is thought to be poisonous but at certain dosage levels it does have medical benefits.

It is very essential to understand the physiological role and mode of action of the functional molecule. At times there could be an interaction with another nutrient or molecule or a drug.

The following principles should be considered for the addition of dietary active compounds in foods.

- 1. The active compound should be present at a level which will not result in either excess or insignificant intake.
- 2. Should be sufficient to exercise its beneficial effect.
- 3. Should not result in an adverse effect on the metabolism of any other nutrient
- 4. Should be stable in food under customary conditions of packaging, storage, distribution and use.
- 5. Should be biologically available from the food
- 6. Methods of measuring should be available

Presently there are a number of ingredients available globally but there is a lack of data on Indian population and to extrapolate the data from foreign countries is not an exact fit. For any study, there is a need to identify the target population — Indian men/ women/ children or elders. Clinical studies either randomized or non randomized adequately powered studies are required before one concludes and claims that a functional ingredient has a significant health benefit. This becomes mandatory before a health claim or a content claim is made. The best method is to conduct a comparative study of placebo vs nutraceuticals, or a comparison between a low dose Vs high, traditional Vs Nutraceutical. Clear cut end point or outcomes are recorded.

To translate new knowledge into a product the entire process of ensuring safety and quality, evaluating the efficacy, mechanisms of action and demonstrating specific health outcomes is absolutely necessary before the product is made available and to make a health claim.

## **Proprietary Foods – Balancing diversity with safety**

#### By Dr. Lewis J.I

A recent spate of advisories requiring proprietary foods to be approved prior to grant of license once again raised the prejudice with which these foods are viewed. It reiterates the over 40 year presumption that proprietary foods are in some way of inferior quality, dubious composition and unwittingly unsafe. Never mind that there isn't any published evidence of how these foods compare with standardized foods.

Proprietary foods are not a 'category of foods' sharing certain common attributes (like food supplements) or marketed to certain target groups (e.g. foods for special dietary uses) – it represents an enabling 'provision' in food law to develop and market food products in an unencumbered manner within the applicable regulations. It is therefore important to understand why proprietary foods are kept away from standardization. There is some historical wisdom – which may be worthwhile, a revisit.

Certain statutes in food law provide the regulator the power to promulgate a definition and standard of identity for foods and enforce the same. Some such standards are found under the erstwhile Appendix B now transposed in to the Food Safety and Standards (Food Products and Food Additives) Regulation 2011. During the war period control on food products was focussed on preventing economic fraud and to ensure that products using certain names meet a specified compositional requirement – e.g. jam (minimum fruit content), margarine (minimum fat content), chocolate, milk etc.

Standardization as a provision in law has twofold effects – it freezes product value and secondly it creates a mindset of exclusive appropriation. How does this happen? Every member of Industry will have an experience of these two phenomena as we read on.

Once a product standard is promulgated it freezes for all time what the product can contain and locks out any form of innovation or improvement. It creates an exclusion zone effect that prevents any other food ingredient, nutrient or additive from being added, no matter how beneficial the improvement is to the consumer. For example the product name "atta' in any labelled food will attract the attention of being violative of the standard if it did contain ingredients or additives not specified by regulation, even if the product is wholesome, nutritionally superior and labelled truthfully. Seemingly while the regulator in the first place standardized the product atta to protect consumer interest – it disengages itself thereafter without updating itself of technological advancements or population health issues that the product may be able to deliver.

For example in the case of fortified atta, if you were to add another vitamin (say Vitamin D) which may be nutritionally more beneficial to children instead of those specified in the standard, and you labelled the product 'Fortified Atta' you run the risk of being in contravention of the law. As a result no nutritional or improved dough rheology additive may be added unless the regulation permits the same. The standard freezes product atta for all time until the regulator changes it - and herein lies the vice like control on food innovation and product development. And the premise of the regulation namely protecting consumer interest fades into oblivion.

When a food is not standardized (read proprietary food) and if a manufacturer wished to improve his product by adding a new ingredient he could do so as long as the ingredient was safe for use and declared on the label. However with the existence of a standard the manufacturer would not do so regardless of the benefit to the consumer unless or until the standard is changed – a long and laborious process.

Another reason why product standards remain cast in stone is because neither the regulator nor the manufacturer attends to its improvement. For example if the manufacturer applies for an amendment it is viewed as insignificant if the same is not supported by the trade to which he belongs or chambers of commerce. Why would an innovative manufacturer wish to disclose his art or patent well in advance to his competitors rather than being first to the market? In most cases it is impractical, impossible and inadvisable to seek amendments considering an ambiguous, discouraging and slothful process. When there is no guarantee of a responsive process, no Food R & D would want to spend time, effort and money in developing a product (let alone a fast track development) when the road to market is fraught with uncertainty and high probability of rejection. An unresponsive regulatory process kills the spirit of new product development.

Another implication of the standardization process is the creation of the 'exclusive appropriation' mindset. A full understanding of this implication of the 'standardization effect' can be appreciated from another applicable rule that a food is misbranded if it purports to be or is represented to be or is being sold by a name which belongs to another article of food (FSSA 2006, 3zf).

What is being elaborated here is how the so called 'exclusive appropriation' mindset extends beyond the construct of the standard. A standard may "illegalize" a perfectly good and honestly labelled product. If a product is developed within the proximity of a standardized food, the developed food runs the risk of being misbranded if it 'purports to be or is represented' as a food for which a standard has been promulgated, no matter how clearly the ingredients or name is stated on the label. The contradiction in terms is evident when proprietary foods are required to provide the name and/or category of the food – obviously the manufacturer's product must bear a name from which the consumer can readily recognise the consumption occasion (like breakfast cereal, carbonated beverage) or usage (like atta, or salt).

Some years back the name protein rich (paushtik) atta could not be used if soy flour was used as the protein source instead of groundnut flour until the standard was amended. Soy flour has a better amino acid profile and yet this benefit is denied to consumers in a standardized food. Similarly 'caffeine' is appropriated to carbonated beverages and 'iodized'

to salt. If any other product no matter how truthfully it is labelled will be held in violation despite the fact that consumers assign same values to "caffeine" and "iodized" in which ever food product they find the ingredient labelled and are not concerned about the exclusivity of standardization.

In reality this is how the 'exclusive appropriation' plays out with every industrial food research and development department. If an innovative ingredient were discovered or developed and as a result a new product is created for the market and is entirely wholesome, delicious, distinctly labelled and superior to anything in the market, you have to be sure and at your own risk that it will not be held as 'purporting to be or as representing a food' for which a standard has been promulgated.

Let us look at a hypothetical example - mayonnaise and salad dressing. Assume that mayonnaise is a standardized product under the rules and a manufacturer seeks to place a product called 'salad dressing' on the market. Because both products are similar in appearance, taste, flavour, presentation, packaging and purpose of use, it could well be held that 'salad dressing' purports to be or is represented as mayonnaise. Therefore under this hypothetical case, since salad dressing purports to be mayonnaise and mayonnaise is a standardized product, you could be in violation.

One can see the sweeping effect such an interpretation of a standardized food can have on other foods. The "standardization mindset" has created such a menacing proposition to product development that even if a company's food R&D developed an exciting product, the legal or regulatory affairs department will inform it of the treacherous road ahead and that no time commitment can be given on the date to market if an amendment is required. Even the testing of the product in the market place raises apprehensions of being in violation. Freedom to innovate is stifled at birth. At every step a regulatory hurdle looms primarily because of the standardization mindset.

Many food product developers feel that the standardization effect has definitely slowed down or prevented progress and improvements which in turn has not been to the consumers' advantage.

Proprietary foods as a provision in law enable initiative and improvement and allow consumers to receive the benefits of innovations. The provision must retain its entity in law if the food industry is to prosper and grow.

#### **Ingredients for Mood Support**

#### Research lends credence to the use of several nutraceuticals for depression and anxiety

Depression affects about 10% adults (about 30 million people as per Centre for Disease Control). Thus this sector rakes in big money for pharma industry. According to IMS Health, sales for antidepressants surpassed \$11 Billion in 2010 making them third most-commonly prescribed drugs in the US. It is also estimated that about 20-45% antidepressant users fail to respond to treatment and about 5 to 20% stop using them due to severe adverse effects. As a result, doctors and patients are likely to explore alternative medicine.

In terms of stress, number of Americans with stress and anxiety continues to rise. Majority of Americans reported having moderate to high levels of stress. This has tremendous impact on society not only because stress can affect a person's quality of life but it also negatively impacts a person's health both physically and psychologically. Americans continue to have high levels of stress.

A survey conducted found depression or anxiety to be number one reason older adults turning to prescription or illicit drugs or alcohol. This is fuelled by stressors such as financial worries and retirement. It is easier for consumers to walk into doctor's office, tell a doctor they are depressed or anxious and walk out with a prescription they think will solve their problems. It takes more work for consumers to find right supplement to help them with these daunting issue, but if they are ready to spend some time doing research they can end up with supplement that can truly help.

In the last decade, supplements like St. John's Wort, SAMe, B vitamins, kava, gamma-amino butyric acid (GABA) and many others have been studies for their effects on stress and depression. Most recently two nutrients – curcumin and omega 3 fatty acids have emerged with promising results.

#### **The Curcumin Connection**

A study published in Acta Poloniae Pharmaceutica compares a highly absorbable form of curcumin from turmeric to fluoxetine (Prozac) and imipramine (Tofranil) in animal model of depression and finds curcumin to be as effective as either prescription drug at alleviating depression. The antidepressant-like activity could be due to an increase in serotonin, norepinephrine and dopamine levels in the brain. Authors added that curcumin can be a useful antidepressant especially in cases which respond to drugs having mixed effects on serotonin and catecholamines levels in the brain.

The form of curcumin studied BCM-95 curcumin has been shown in human studies to have 10 times absorption as standard curcumin with no significant adverse safety issues. Lead author Dr. Anthony commented that it does not matter how much one takes but how much one absorbs. BCM-95 not only is better absorbed but also in similar ratios of curcuminoids are absorbed as they occur in nature.

#### **Omega 3 for Anxiety**

Anxiety often accompanies depression. Studies have confirmed the biological link between stress, anxiety and depression. Researchers from Ohio State University published a study in Brain, Behaviour & Immunity regarding omega 3s effect on anxiety. Over the course of 12 weeks, researchers gave 68 medical students 2085 mg eicosapentaenoic acid (EPA) and 348 mg docosahexaenoic acid (DHA) or a placebo to determine if fish oil had the ability to decrease proinflammatory cytokine production and depressive and anxiety symptoms. The supplements the students received were the equivalent of four to five times the amount of fish oil one would get from an average daily serving of salmon.

Psychological stress was repeatedly shown to increase cytokine production and since omega 3 can reduce level of cytokines in body, researchers wanted to see the effect of omega 3 in reducing depression by reducing inflammation.

The study showed clearly an important change in anxiety among students. Those receiving the omega 3 showed a 20% reduction in anxiety compared to placebo group.

Blood sample analysis showed a 14% reduction in cytokine interleukin-6 among students receiving omega 3. The study demonstrated the positive role of omega 3 supplements in reducing both anxiety and inflammation, but researchers recommended that people should get their omega 3 through their diet rather than daily supplements. They also commented that the elderly and people at high risk for certain diseases might also benefit even more that the young participants of the study.

#### **Other Options**

When the body is stressed many stress-related symptoms occur due to an increase in stress hormone cortisol. Branded ingredient Sensoril provides resistance to stress as it contains glycowhithanolide bioactives that reduce cortisol levels in body. In a human clinical trial, consumption of Sensoril resulted in 24% reduction in cortisol levels accompanied by 70% reduction in overall measure of stress-related symptoms as well as improvement in factors affected by stress including irritability and anxiety, cognitive function, sleeplessness etc.

Another mood support contender is another patented nutraceutical Lactium that effectively addresses stress sensation and sleep which thus supports healthier mood promoting relaxation. Studies conducted on 90 healthy individuals confirms anti-stress efficacy.

Relora, developed from Magnolia officinalis and Phellodendron amurense, natural ingredients used in Traditional Chinese medicine, helps alleviate stress and stress-related eating. It helps quiet that part of brain responding to stress without causing drowsiness.

#### Kava (Piper methysticum): One of the Safest Ways to Treat Anxiety

Anxiety when not severe is manageable with supplements as many medicines have undesirable side effects. Kava has been shown to be useful in such treatments and is accepted by medical community and a recent meta-analysis of studies on use of kava for anxiety treatment shows that kava extract is effective in symptomatic treatment for anxiety. A decade ago some cloud on safety of kava was there with claims of liver damage, but later it turned out to be due to excess drug and alcohol consumption as well as self-medication while using kava. It has been shown that kava interacts poorly with alcohol. When kava is taken safety, in absence of alcohol, it is without side-effects and is not addictive.

Kava is most effective when a person is willing to make lifestyle changes and eat a healthy diet. Kava can and will mitigate a large percentage of anxiety.

From Nutraceuticals World May 2012 based on articles by Joanna Cosgrove, Rebecca Wright & Ryan Rivera

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#### **Nurturing Women's Needs**

Today's holistic-minded marketplace has brought in certain awareness. Before women think of visiting doctor, often they opt for natural, readily available alternatives to remedy their health concerns. They rely on dietary supplements and functional foods to sustain mind/body wellness thinking about prevention rather than cure. Factors like diet, exercise, genetics and even habit play vital roles in overall wellbeing. Following health concerns are important to women namely weight loss, digestive irregularity and cancer prevention. Additionally, pregnancy and menopause, important stages in women's life, bring abundant changes of physical changes creating additional concerns.

New study on pycnogenol shows it significantly improves signs and symptoms of menopause, including hot flashes, night sweats and mood swings among others. The study also found that it decreases bloating and improved irregular heart beat and digestive problems. A study also showed that women are more acutely aware of their own health and when it comes to supplements, women take charge. There are more women taking supplements than men.

#### **Down to the Bones**

As per National Osteoporosis Foundation, as estimated 8 million women have osteoporosis and millions of others have low bone mass and prone to the risk. Although osteoporosis is associated with older women, it may hit occur any time during woman's life. Although calcium and vitamin D help build strong bones and prevent onset of osteoporosis, they are not the only key components. The mix of minerals with calcium, magnesium and trace minerals and uptake are important to support bone and joint health. It is also known that prebiotics increase mineral absorption.

Prebiotic fibre inulin can be incorporated into almost any food or beverage without affecting taste or texture. Research has shown that inulin may enhance dietary calcium absorption particularly among pre-teens and post-menopausal women. Inulin also supports natural healthful bacteria in the lower GI tract. Inulin and probiotics make a strong team for any digestive health product.

#### **Nature's Health Warriors: Probiotics**

Consumers are becoming increasingly aware of the multifaceted benefits of probiotics. In addition to digestive and feminine health benefits, they have additionally been linked to immune enhancement and even cancer prevention. Women look feminine health concerns like yeast infections and food and supplements have a huge impact on these health issues. Sometimes clever advertising may fool them so they should always read labels to find out the claims and benefits. Companies have been responding to consumer demands for probiotics in a wide variety of foods and drinks, even probiotic flavoured waters if consumers do not want dairy products.

#### **Heart & Mindsets**

Superfoods, usually derived from fruits and vegetables such as broccoli, pomegranate and blueberries with intense colours are being touted as nature's miracles due to antioxidants which protect cells from free radical damage and thus might boost immunity and possess anti-aging properties.

Heart disease is number one killer of women. Aside from super foods, another way of warding off the disease is a diet that is low in carbohydrates and saturated fats but high in fibre, fruits and vegetables. Another effective way of sticking to these guidelines while on the run is eating protein rich snack bars that boost antioxidants and fibre.

Green tea is considered a superfood packed with polyphenols, rich antioxidants that help fight certain cancers. They are also known to strengthen the cells lining the blood vessels helping reduce the risk of heart disease. In addition green tea extract is also available for food, beverages and supplements.

Once women enter menopause increased levels of cholesterol are triggered. Products containing plant sterols have been clinically shown to lower cholesterol.

#### **Labels & Getting Back to Nature**

Consumers are going back to foods as source of nutrition than supplements. People want their nutrients from whole foods and then from supplement for nutrients that cannot be readily found in whole foods. They want nutrient dense cereals which are unprocessed and thereby preserve the nutritional integrity of the whole grains. They want clean ingredient label they can read and understand. They would like to eat from a package is something they could also make at home. Things with isolate, fortifications and funny sounding names are becoming a turnoff for women.

Pregnant women are extremely mindful about the ingredients they select for their increased nutritional requirements. Both mother and child need a special type of nourishment. Baby's red blood cells and development are dependent on protein and folic acid for brain development. Calcium is good for bones and iron helps promote weight gain in baby and support healthy blood cells in mom.

#### The Wave of the Future: 'Free-From' Foods

According to Mintel, new products targeting allergies are important for women. Most women treating allergies used products that didn't require a prescription. The study also showed that women often shopped for the household and also that one person had food allergy, it usually influenced the nutritional habits of three to four other individuals. Free-from foods may include a range of products that don't contain sugar or soy to the popular category of gluten-free. Celiac disease affects 3 million Americans and the only known treatment is gluten-free diet. Gluten-free market in 2011 was over \$6 billion. The market is expanding beyond those diagnosed with celiac. People are taking gluten-free diet for many reasons like looking to feel better, less bloating and other stomach issues.

It is surprising how many products contain gluten and since cooking gluten-free at home is difficult, women choose to purchase products already prepared. Here also people are more attracted to real food as opposed to those created in lab. Because of the increasing awareness of gluten intolerance problem, more suppliers are offering newer products. This has spread to restaurants also that are putting gluten-free meals and make sure there is no cross contamination in the kitchen.

#### **Go Light on the Sugar Please**

American Diabetes Association estimates nearly 11% of all women aged 20 years and over have diabetes. With some scientific research showing adverse side effects associated with artificial sweeteners, more people are opting to go the natural route. Over 60% American adult women are overweight so weight loss market has grown to over \$60 billion as per Marketdata Enterprise 2011 data. As women move away from artificial sweeteners in favour of natural option, Mintel predicts that stevia, natural calorie-free sweetener will see its market double by 2013 reaching about \$1.2 billion.

#### **Make it Simple**

As women aspire for wellness and veer away from conventional medicines to treat diseases, they will be looking for organic and whole food choices coupled with informed choices in nutritional supplements. They will read labels with critical eye, expecting ingredients they can trust and understand. Straightforward approach to nutrition fosters simplicity focused on pure, most effective ingredients possible for the health concerns. If this new attitude is noted and some awareness about science behind these ingredients is created, it will not be very difficult to grow the market.

Condensed from an article in Nutraceuticals World May 2012 by Danielle Winston

### **Research in Health & Nutrition**

#### Study: Vitamin K Benefits Bone, Cardiovascular Health

May 24, 2012 Food Product Design

OSLO—Natto Pharma announced the presentation of the recently completed 3-year clinical trial investigating beneficial effects of nutritional doses of natural vitamin K2 (MenaQ7®) on bone and vascular health. During Vitafoods 2012, Dr. Cees Vermeer, principal investigator at Vita K laboratory at Maastricht University, presented data showing significant benefits for improved bone strength and prevention of cardiovascular aging with daily supplementation of MenaQ7.

In the study, 244 healthy postmenopausal women received for three years daily 180 µg K2 from MenaQ7 or a placebo. The clinical measurements included bone mineral density, bone strength, vascular characteristics by ultrasound and pulse-wave velocity (PWV), the latter evaluating age-related stiffening of blood vessels.

MenaQ7 supplementation provided a statistically significant protection of the most vulnerable bone structures i.e. vertebrae and the hip. One of the important findings from the study was that clinically relevant improvement at the site of the femoral neck became evident no sooner than after two and three years of MenaQ7 supplementation. This finding explains for the first time why shorter studies typically failed to show benefits of vitamin K on bone health and cardiovascular health.

The MenaQ7 trial showed significant benefits in preventing age-related stiffening of arteries resulting in increase of the PWV in the placebo group, but not in the MenaQ7-group. MenaQ7 not only prevented stiffening, it also resulted in an unprecedented statistically significant improvement of vascular elasticity both measured with ultrasound techniques and PWV. Previously the positive effects on bone and vascular health have been demonstrated with a pharmacological dose of synthetic forms of vitamin K, of up to 45 milligrams per day. The MenaQ7 study shows for the first time in history of vitamin K evaluation the positive health effects with a "nutritional" dose of vitamin K. The low-dose MenaQ7 effects were even more pronounced than those in trials using a high dose of one of the synthetic forms of vitamin K.

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#### Saturated Fats Speed Up Cognitive Decline in Women

May 23, 2012 Food Product Design

BOSTON—Women who consume a diet high in saturated fats, such as those found in meat and dairy products, may experience faster cognitive decline over time compared to women who eat a diet rich in monounsaturated fats found in plant foods, such as avocados and olive oil, according to a new study published in the Annals of Neurology.

Researchers at Brigham and Women's Hospital (BWH) analyzed data from 6,183 women over age 65 who participated in the Women's Health Study. The women participated in three cognitive function tests spaced out every two years for an average testing span of four years. Participants filled out detailed food frequency surveys at the start of the Women's Health Study, prior to the cognitive testing.

"When looking at changes in cognitive function, what we found is that the total amount of fat intake did not really matter, but the type of fat did," said lead author Olivia Okereke, MD, MS, BWH Department of Psychiatry.

Women who consumed the highest amounts of saturated fat, which can come from animal fats, such as red meat and butter, compared to those who consumed the lowest amounts, had worse overall cognition and memory over the four years of testing. Women who ate the most of the monounsaturated fats, which can be found in olive oil, had better patterns of cognitive scores over time.

"Our findings have significant public health implications," Okereke said. "Substituting in the good fat in place of the bad fat is a fairly simple dietary modification that could help prevent decline in memory."

#### **Daily Dose of Dark Chocolate Boosts Heart Health**

June 1, 2012 Food Product Design

VICTORIA, Australia—Individuals who eat dark chocolate on a daily basis lower their risk for stoke and heart attack by nearly 30%, according to a new study published in the *British Medical Journal*. The findings suggest flavonoids in dark chocolate work to lower blood pressure and cholesterol.

Researchers at Monash University examined the association between eating 100g of dark chocolate every day over a 10-year period. They were particularly interested in the long-term health benefits of flavonoids on cardiovascular health.

They used a mathematical model to predict the long-term health effects and cost effectiveness of daily dark chocolate consumption in 2013 people already at high risk of heart disease. Participants had no history of heart disease or diabetes and were not on blood pressure-lowering therapy.

"Our findings indicate dark chocolate therapy could provide an alternative to or be used to complement drug therapeutics in people at high risk of cardiovascular disease," they said. "We're not suggesting that the high-risk group use dark chocolate as their only preventative measure, but in combination with sensible choices, such as exercise."

Their findings suggested that investing \$42 per person, per year on dark chocolate-related health strategies, including advertising and promotion, would be beneficial to the wider population in the prevention of cardiovascular disease.



#### **Low Maternal Folic Acid Intake Ups Autism Risk**

June 11, 2012 Food Product Design

DAVIS, Calif.—Maternal intake of folic acid early in pregnancy has been shown to significantly decrease the risk of autism compared to women who did not get adequate amounts through food or supplements, according to a new study published in the American Journal of Clinical Nutrition. The findings suggest daily intake of 600 micrograms ( $\mu$ g) of folic acid for the first month of pregnancy was associated with a 38% lower chance of having a child autism or Asperger's.

Researchers at the University of California Davis Medical Investigation of Neurodevelopmental Disorders Institute investigated the association between maternal folic acid intake and the risk of autism spectrum disorder (ASD) and developmental delay (DD).

For the study, researchers surveyed mothers of 429 preschoolers with an autism spectrum disorder and 278 with normal development about their diet and supplement use before and during pregnancy who had enrolled in the CHARGE (Childhood Autism Risks from Genetics and Environment) Study from 2003 to 2009. Average daily folic acid was quantified for each mother on the basis of dose, brands, and intake frequency of vitamins, supplements and breakfast cereals reported through structured telephone interviews.

Results showed mothers of children without autism got more folic acid through fortified foods and vitamins during their pregnancies compared to those who had an autistic child. Results were the greatest in the first month of pregnancy, when mothers of normally-developing babies had an average daily intake of 779  $\mu$ gof folic acid daily, compared to an average 655  $\mu$ g in moms of autistic kids.



#### 3 Cups of Coffee Daily Delays Alzheimer's Onset

June 19, 2012 Food Product Design

ST. PETERSBURG, Fla. and MIAMI—Older individuals with mild cognitive impairment (MCI) who drink up to three cups of coffee a day may help ward off progression to full-blown Alzheimer's disease by up to two to four years compared to those who consume less caffeine, according to a new study published in the *Journal of Alzheimer's Disease*.

Researchers from the University of South Florida and the University of Miami collaborated on the study to investigate how caffeine/coffee intake is associated with a reduced risk of dementia or delayed onset. The study involved 124 people, ages 65 to 88, in Tampa and Miami who had mild cognitive impairment (MCI). About 15% of people with MCI develop full-blown Alzheimer's disease each year.

Blood caffeine levels at the study's onset were substantially lower (51% lower) in participants diagnosed with MCI who progressed to dementia during the 2- to 4-year follow-up than in those whose mild cognitive impairment remained stable over the same period. No one with MCI who later developed Alzheimer's had initial blood caffeine levels above a critical level of 1n200 ng/ml—equivalent to drinking several cups of coffee a few hours before the blood sample was drawn. In contrast, many with stable MCI had blood caffeine levels higher than this critical level.

"We found that 100% of the MCI patients with plasma caffeine levels above the critical level experienced no conversion to Alzheimer's disease during the 2- to 4-year follow-up period," said study co-author Dr. Gary Arendash.

The researchers said higher blood caffeine levels indicate habitually higher caffeine intake, most probably through coffee. Caffeinated coffee appeared to be the main, if not exclusive, source of caffeine in the memory-protected MCI patients, because they had the same profile of blood immune markers as Alzheimer's mice given caffeinated coffee. Alzheimer's mice given caffeine alone or decaffeinated coffee had a very different immune marker profile.

According to the U.S. Census Bureau, the 65-and-over population will reach 88.5 million by 2050, making them an ideal market for beverages that fuel their golden years. Check out the "Beverages for Healthy Aging" in **Food Product Design's** Content Library to learn more about what's trending in that category.



#### **Ginger Promotes Satiety in Overweight Men**

June 22, 2012 Food Product Design

NEW YORK—Overweight men who incorporated a ginger drink into their morning meals had a lower prospective food intake later in the day and reduced hunger, according to a new study published in the journal *Metabolism*. The findings suggest ginger may play a potential role in overall weight management by increasing satiety without any adverse side effects.

Researchers at Columbia University and the New York Obesity Research Center gave 10 healthy but overweight men a standard breakfast accompanied by a ginger "tea" with 2 g of dried ginger powder (equivalent to about 1 teaspoon) or the same breakfast with plain hot water on two separate days. Researchers documented feelings of hunger immediately before and hourly after breakfast consumption, the calories burned after eating (thermic effect of food) as well as other measures.

They found approximately 43 more calories were burned after eating but total resting energy expenditure and respiratory quotient were not significantly affected. There were also no ginger-related effects on blood glucose, insulin, triglycerides or a variety of other metabolic parameters.

While more research is needed to understand the role of ginger in weight management, the researchers concluded including powdered ginger in the diet could have a small but significant effect on how food is processed in the body and "influence feelings of satiety without any adverse side effects."



#### **Dessert For Breakfast Increases Satiety, Reduces Weight Gain**

June 26, 2012 Food Product Design

HOUSTON—Eating a carbohydrate-rich, protein-packed breakfast that includes dessert helps dieters maintain the feeling of fullness throughout the day and keep snacking at bay, according to new research presented at The Endocrine Society's 94th Annual Meeting.

The findings, published in the journal Steroids, suggest enriched breakfast may be a key to maintaining weight loss and preventing weight regain over time.

Researchers at Tel Aviv University's Wolfson Medical Center studied nearly 200 non-diabetic obese adults who were randomly assigned to eat one of two low-calorie diets. Both diets had the same number of daily calories—about 1,600 for men and 1,400 for women—but differed mainly in the composition of breakfast. One group received a low-carbohydrate diet, featuring a 304-calorie breakfast with only 10 grams of carbs. The other group ate a 600-calorie breakfast with 60 grams of carbs, which included a small sweet, such as chocolate, a doughnut, a cookie or cake. Both diets contained protein (such as tuna, egg whites, cheese and low-fat milk) at breakfast, but the "dessert with breakfast diet" had 45 grams of protein, 15 grams more than in the low-carb diet.

Halfway through the eight-month study, participants in both groups lost an average of 33 pounds per person. In the last four months of the study, the low-carb group regained an average of 22 pounds per person, while participants who ate the dessert with breakfast diet lost another 15 pounds each.

In addition, the study subjects who ate the dessert with breakfast diet reported feeling less hunger and fewer cravings compared with the other group. Subjects' food diaries showed that the dessert with breakfast group had better compliance in sticking to their calorie requirements. Women who ate the dessert with breakfast diet were allowed 500 calories for lunch and about 300 calories for dinner. Men in that group could eat a 600-calorie lunch and up to 464 calories at dinner.

Ghrelin levels were reduced after breakfast by 45.2% on the high-carb protein diet versus 29.5% for those on the low-carb diet. Satiety was significantly improved and hunger and craving scores significantly reduced in the high-carb protein diet group versus the low-carb diet group.



#### Low Vitamin D Linked to Weight Gain in Older Women

June 26, 2012 Food Product Design

PORTLAND, Ore.—Older women with insufficient levels of vitamin D have a higher chance of gaining weight over time compared to those who have adequate levels, according to a new study published in the *Journal of Women's Health*.

The study of more than 4,600 women ages 65 and older found that over nearly five years, those with insufficient levels of vitamin D in their blood gained about two pounds more than those with adequate levels of the vitamin.

"This is one of the first studies to show that women with low levels of vitamin D gain more weight, and although it was only two pounds, over time that can add up," said study author Erin LeBlanc, MD, an endocrinologist and researcher at the Kaiser Permanente Center for Health Research. "Nearly 80% of women in our study had insufficient levels of vitamin D. A primary source of this important vitamin is sunlight, and as modern societies move indoors, continuous vitamin D insufficiency may be contributing to chronic weight gain."

The study was conducted among older women who, for the most part, were not trying to lose weight--though some of them did so as a natural result of aging. About 60% of the 4,659 women in the study remained at a stable weight (within 5% of their starting weight) over the 4.5-year study period, 27% lost more than 5% of their body weight, and 12% gained more than 5% of their body weight.

Most women in the study (78%) had less than 30 nanograms per millimeter (ng/ml) of vitamin D in their blood—a level defined as sufficient. The women had higher baseline weight to begin with—148.6 pounds—compared to 141.6 pounds for women whose vitamin D levels were 30 ng/ml or above. Insufficient levels had no association with weight changes in the entire group of women, or in the group that lost weight; however, the group of 571 women who gained weight, those with insufficient vitamin D levels gained 18.5 pounds over five years compared to women who had sufficient vitamin D levels. That group gained 16.4 pounds over the same period.



#### **Concord Grape Juice Boosts Cognition in Older Adults**

June 21, 2012 Food Product Design

CINCINNATI—Drinking a glass of polyphenol-rich Concord grape juice may help boost neurocognitive function in older adults with mild memory decline, according to a new study published in the *Journal of Agricultural and Food Chemistry*.

Polyphenol compounds found in berry fruits, in particular flavonoids, have been associated with health benefits including improvement in cognition and neuronal function with aging. Concord grape juice contains polyphenols, including anthocyanins and flavanols, and previous research has shown improvement in a number of human health conditions with grape juice supplementation.

For the study, researchers at the University of Cincinnati Academic Health Center enrolled older adult subjects (average age 77) with mild cognitive impairment in a randomized, double-blind, placebo-controlled study. Participants consumed Concord grape juice or placebo daily for 16 weeks and were administered assessments of memory function and brain activation pre- and post-intervention.

Participants who consumed grape juice showed reduced semantic interference on memory tasks. Relatively greater activation in anterior and posterior regions of the right hemisphere was also observed with functional magnetic resonance imaging in the grape juice treated subjects. These findings provide further evidence that Concord grape juice can enhance neurocognitive function in older adults with mild memory decline.



#### Milk Ingredient Does a Waistline Good

Science Daily (June 5, 2012) — A natural ingredient found in milk can protect against obesity even as mice continue to enjoy diets that are high in fat. The researchers who report their findings in the June *Cell Metabolism*, a Cell Press publication, liken this milk ingredient to a new kind of vitamin.

"This is present in what we've all been eating since day one," says Johan Auwerx of École Polytechnique Fédérale de Lausanne.

The researchers identified this ingredient, known as nicotinamide riboside, as they were searching for alternative ways to boost the well-known gene SIRT1, which comes with benefits for both metabolism and longevity. One way to do that is to target SIRT1 directly, as the red wine ingredient resveratrol appears to do, at least at some doses.

Auwerx's team suspected there might be a simpler way to go about it, by boosting levels of one of SIRT1's molecular sidekicks, the cofactor NAD+. This milk ingredient does just that in a rather appealing way. Not only is it a natural product, but it also gets trapped within cells, where it can do its magic. Mice that take nicotinamide riboside in fairly high doses along with their high-fat meals burn more fat and are protected from obesity. They also become better runners thanks to muscles that have greater endurance.

The benefits they observe in mice wouldn't be easy to get from drinking milk alone, Auwerx says. It may be more likely that the compound would serve as a new kind of metabolism-boosting supplement. Tests done in people are now needed to help sort out those details.

On the other hand, he says, this milk substance ultimately offers the same benefits attributed to resveratrol, but in a different way. It's possible that many small effects of ingredients found in our diets could add up to slimmer waistlines -- perhaps longer lives, too.



#### **'Bad' Dieting Increases Cardiovascular Disease Risk**

Science Daily (June 10, 2012) — A 25 year study in Northern Sweden, published in BioMed Central's open access journal *Nutrition Journal*, is the first to show that a regional and national dietary intervention to reduce fat intake, decreased cholesterol levels, but a switch to the popular low carbohydrate diet was paralleled by in an increase in cholesterol levels. Over the entire 25 year period the

population BMI continued to increase, regardless of either diet, and both the increase in body mass and increased cholesterol levels are indicators of increased cardiovascular risk.

In the 1970's it was noticed that the incidence of cardiovascular disease was higher in northern Sweden than anywhere else in the country and that for men it was amongst the highest in the world. The Västerbotten Intervention Programme (VIP) was set up in 1985 to address this and was later extended to include the entire country. The VIP included better food labelling, healthy information, cooking demonstrations and health examinations and counselling, including diet advice, and still continues today.

Evaluation of this program was combined with data from the WHO MONICA project which monitors cardiovascular disease risk factors. Researchers from Umeå University, University of Gothenburg, and The National Board of Welfare collaborated to review this information covering a 25 year period from 1986.

The impact of the VIP was clearly seen in the changing intake of fat and carbohydrate. By 1992 the fat intake for men had reduced by 3% for men and 4% for women and remained stable until 2005. Not only did fat intake reduce due to VIP but the types of fat changed, for example from butter to low fat spreads, which was mirrored by a decrease in cholesterol levels. After 2005 the levels of total and saturated fat intake began to increase, returning to levels above those in 1986, and the amount of complex carbohydrates eaten decreased. The timing of this matched the promotion of low GI diets in the media. Consequently cholesterol levels began to once more increase despite the introduction of cholesterol lowering medication.

Prof Ingegerd Johansson, who led this research, commented, "The association between nutrition and health is complex. It involves specific food components, interactions among those food components, and interactions with genetic factors and individual needs. While low carbohydrate/high fat diets may help short term weight loss, these results of this Swedish study demonstrate that long term weight loss is not maintained and that this diet increases blood cholesterol which has a major impact on risk of cardiovascular disease."



#### Diet, Exercise or Both? What Obese Older Adults Need to Do to Reduce Cardiometabolic Risk

Science Daily (June 25, 2012) — Obese older adults can reduce their chance of developing the metabolic syndrome by losing weight through dieting alone, but adding exercise to a weight loss program has even more benefit, a new study finds. The results, presented June 25 at The Endocrine Society's 94th Annual Meeting in Houston, show that a combination of diet-induced weight loss and frequent exercise almost doubled the improvement in insulin sensitivity compared with dieting alone.

The metabolic syndrome is a cluster of metabolic problems that raise the risk of Type 2 diabetes and heart disease: abdominal obesity as shown by a large waist circumference, disturbed lipids (low HDL or "good" cholesterol and high triglycerides), high blood pressure and high blood glucose (blood sugar). Although it is known that weight loss can reduce these risk factors, the most appropriate lifestyle treatment for obesity in older adults has been controversial, said the presenting author, Matthew Bouchonville, MD.

"It was not clear from prior studies in obese elderly adults whether the beneficial effects of diet and exercise are distinct from each other or have additive effects," said Bouchonville, an assistant professor at the University of Mexico Health Sciences Center and the New Mexico Veterans Affairs (VA) Health Care System in Albuquerque.

The researchers investigated the independent and combined effects of diet-induced weight loss and regular exercise in a one-year randomized controlled clinical trial, funded by the National Institute on Aging. They randomly assigned 107 obese adults ages 65 and older to one of four groups: weight management using a calorie-restricted diet, exercise (three times a week for 90 minutes each) without dieting, combined dieting with exercise, and controls (no diet or exercise).

The primary outcome analyzed was the degree of change in the insulin sensitivity index. Insulin sensitivity is the body's ability to successfully clear glucose from the bloodstream and is often impaired in obese people. This index was measured from the oral glucose tolerance test, a blood test for diabetes after the patient drinks a sugary drink.

Other measures obtained included those for the components of the metabolic syndrome as well as C-reactive protein, a measure of inflammation. Research has linked chronic inflammation to diabetes and heart disease.

Ninety-three participants completed the study. In the intention-to-treat analysis of all 107 subjects, the insulin sensitivity index did not improve in the exercise-alone group or the controls. This index did improve on average by 40 percent in the diet group and by 70 percent in the combined diet-exercise group after controlling for relevant covariates, Bouchonville reported.

"This suggests a distinct complementary effect of exercise on diet-induced weight loss," he said.

Weight loss by diet alone also led to improvements in blood pressure and C-reactive protein. Without weight loss, exercise did not result in improvement in these risk factors, Bouchonville said. Other measures that did not improve in the exercise-only group or the controls but did improve in the other two groups included glucose and insulin response to the oral glucose tolerance test (levels of insulin and glucose trended over several time points after the sugar intake), waist circumference, abdominal visceral (deep belly) fat, triglycerides and adiponectin. Adiponectin is a protein produced in fat cells that improves insulin sensitivity.

#### Why Does a Diet High in DHA Improve Memory?

Science Daily (June 28, 2012) — We've all heard that eating fish is good for our brains and memory. But what is it about DHA, an omega-3 fatty acid found in fish that makes our memory sharper? Researchers with the Faculty of Medicine & Dentistry discovered a possible explanation and just published their findings in the peer-reviewed journal *Applied Physiology, Nutrition, and Metabolism*.

Principal investigator Yves Sauve and his team discovered lab models fed a high-DHA diet had 30 per cent higher levels of DHA in the memory section of the brain, known as the hippocampus, when compared to animal models on a regular, healthy diet. "We wanted to find out how fish intake improves memory," says Sauve, a medical researcher at the University of Alberta who works in the department of physiology, the department of ophthalmology and the Centre for Neuroscience.

"What we discovered is that memory cells in the hippocampus could communicate better with each other and better relay messages when DHA levels in that region of the brain were higher. This could explain why memory improves on a high-DHA diet."

Sauve noted it is a key finding that when a diet is supplemented with DHA, that additional stores of the omega-3 fatty acid are deposited in the brain. His team confirmed this finding, a discovery other labs have noted as well. Supplementing your diet with DHA, such as increasing fish intake or taking supplements, could prevent declining DHA levels in the brain as we age, says Sauve.

Earlier this year, Sauve and other colleagues discovered DHA prevents the accumulation of a toxic molecule at the back of the eye that causes age-related vision loss. He is continuing his research in this area.

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#### **Curry Ingredient Curcumin May Increase Protein Levels In Immune System**

01 Jun 2012 Medical News Today

The cooking spice turmeric is not only a vital ingredient in many curries, it has also been used for 2,500 years as a medicinal compound in the Ayurvedic system of medicine in India. Now, researchers have discovered that a compound found in the spice called curcumin can increase the levels of a protein known to be vital in the "innate" immune system.

Cathelicidin antimicrobial peptide (CAMP) is a major component in the immune system that helps our bodies fight off various viruses, bacteria or fungi. Although earlier studies have demonstrated that vitamin D increases CAMP levels, researchers are interested in finding an alternative mechanism to influence or increase CAMP levels. The study, conducted by researchers in the in collaboration with researchers from the University of Copenhagen, Denmark, is published in the *Journal of Nutritional Biochemistry* and was funded by the National Institutes of Health.

Adrian Gombart, an associate professor of biochemistry and biophysics in the Linus Pauling Institute, explained: "This research points to a new avenue for regulating CAMP gene expression. It's interesting and somewhat surprising that curcumin can do that, and could provide another tool to develop medical therapies."

Although, curcumin does not increase CAMP levels as significantly as vitamin D, it could have physiologic value, said Gombart.

Researchers have also studied the anti-inflammatory and antioxidant properties of cur cumin. Gombart said: "Curcumin, as part of turmeric, is generally consumed in the diet at fairly low levels. However, it's possible that sustained consumption over time may be healthy and protect against infection, especially in the stomach and intestinal tract."

The researchers set out to determine whether curcumin and omega-3 fatty acids can increase CAMP levels. They found that curcumin increased levels by almost three-fold whereas omega-3 fatty acids did not. The CAMP peptide, which is the only known antimicrobial peptide of its type in humans, appears to have the ability to destroy a variety of bacteria, including those that cause tuberculosis and protect against the development of sepsis.

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#### Osteoarthritis Patients May Benefit From Drinking Tart Cherry Juice

01 Jun 2012 Medical News Today

Tart cherries have the highest anti-inflammatory content of any food, according to researchers, and may help individuals suffering from osteoarthritis manage their disease.

The study, conducted by researchers from Oregon Health and Science University, involved 20 women aged 40-70 with inflammatory osteoarthritis. The study was presented May 30th at the American College of Sports Medicine Conference (ACSM) in San Francisco, California. The researchers found that drinking tart cherry juice two times per day for three weeks resulted in considerable reductions in vital inflammation markers, especially for participants who had the highest inflammation levels at the start of the study.

Lead researcher of the study, Kerry Kuehl, M.D., Dr.PH., M.S., Oregon Health & Science University, said: "With millions of Americans looking for ways to naturally manage pain, it's promising that tart cherries can help, without the possible side effects often associated with arthritis medications. I'm intrigued by the potential for a real food to offer such a powerful anti-inflammatory benefit - especially for active adults."

Osteoarthritis is the most prevalent type of arthritis. According to the Arthritis Foundation, athletes are at particular risk for developing osteoarthritis, due to excessive joint use that can a breakdown in cartilage and lead to pain and injury. Kuehl's previous research suggests that the inflammation benefits of tart cherries, available in dried, frozen and juice forms, could be particularly important for athletes. Kuehl found that individuals who drank tart cherry juice while training for a long distance run experienced considerably less pain after exercise than those who didn't.

The antioxidant compounds in tart cherries, called anthocyanins, provide the fruit's bright color and have been associated to high antioxidant capacity and reduced inflammation, at levels similar to some popular pain medications. A daily dose of tart cherries (as cherry extract) reduced osteoarthritis pain by over 20% in most people, according to results from a study conducted by researchers at Baylor Research Institute. Furthermore, the antioxidant compounds in cherries have also been shown to reduce muscle and joint soreness.

Leslie Bonci, MPH, RD, CSSD, LDN, Director of Sports Nutrition at the University of Pennsylvania Medical Center for Sports Medicine, said: "Why not eat red when there's so much science to support the anti-inflammatory benefits of this Super Fruit? And for athletes whose palates prefer the tart-sweet flavor profile of tart cherries, it's the optimal ingredient."

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#### **Snacking On Raisins Controls Hunger, Promotes Satiety In Children**

04 Jun 2012 Medical News Today

New research recently announced at the Canadian Nutrition Society annual meeting in Vancouver, B.C., suggests eating raisins as an after-school snack prevents excessive calorie intake and increases satiety - or feeling of fullness - as compared to other commonly

consumed snacks.

The study, funded by a grant from the California Raisin Marketing Board, was conducted among 26 normal-weight boys and girls ages 8 - 11 during a three-month timeframe. Study participants were randomly assigned to eat raisins or other snacks, including grapes, potato chips or chocolate chip cookies, until they were comfortably full. Additionally, each child received the same standardized breakfast, morning snack and lunch on test days. Subjective appetite was measured before and immediately after snack consumption at 15-minute intervals. Key study findings include:

- Food intake following raisin consumption was lower and satiation greater compared to the other snacks
- When eating raisins, children consumed significantly fewer calories when compared to the other snacks in the study
- Grapes, potato chips and cookies resulted in ~ 56 percent, 70 percent and 108 percent higher calorie intake compared to raisins, respectively
- Cumulative calorie intake (breakfast + morning snack + lunch + after-school snack) was 10 percent -19 percent lower after raisins compared to other snacks
- Although all snacks reduced subjective appetite, desire-to-eat was lowest after consuming raisins

The study was conducted by lead researcher, G. Harvey Anderson, Ph.D., Professor of Nutritional Sciences and Physiology, Department of Nutritional Sciences, University of Toronto and co-investigated by Nick Bellissimo, Ph.D., Assistant Professor, School of Nutrition, Ryerson University and Bohdan Luhovyy, Ph.D., Assistant Professor, Department of Applied Human Nutrition, Mount Saint Vincent University.

"To our knowledge, this is the first controlled study that looks at after-school snacking and satiety among children," said Anderson. "We found consumption of raisins as a snack prevented excessive calorie intake, increased the feeling of fullness, and thereby may help contribute to the maintenance of a healthy weight in school-age children."

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#### New Insights Into The Health Implications Of Different Types Of Trans Fat

05 Jun 2012 Medical News Today

The latest research builds on ground-breaking new knowledge on a special 'family' of natural trans fats that are produced by ruminant animals such as dairy and beef cattle, goats and sheep, and found in the milk and meat from these animals. The findings strengthen the evidence that, unlike industrial trans fats, these natural ruminant trans fats are not harmful and may in fact have health-enhancing potential. The key findings were presented at the 10th Congress for the International Society for the Study of Fatty Acids & Lipids (ISSFAL).

"We are learning there is a very important public health message to convey about ruminant natural trans fats and how these are different from the industrial trans fats that have been targeted as harmful to health," says Dr. Spencer Proctor, Director of the Metabolic and Cardiovascular Diseases Laboratory at the University of Alberta in Canada. "The research indicates that consuming these natural trans fats as part of a balanced diet is not a health concern. On the contrary, there is increasing evidence these are 'good fats' and could be fundamentally health-enhancing. They should not be an unintended target of the bid to rid the diet of trans fats."

ISSFAL is an International Scientific Society established in 1991, with members from more than 40 countries including scientists, medical professionals, educators, administrators, communicators and others with an interest in the health effects of dietary fats, oils and lipids. Among a number of key functions, ISSFAL has taken on an important role in interpreting the new facts in each of these areas into sound nutritional advice for the public.

Proctor chaired a Symposium at the ISSFAL Congress that focused on the health implications of natural ruminant trans fatty acids. Also presenting supporting findings were Dr. Jean-Michel Chardigny, National Institute for Agricultural Research (INRA), France; and Dr. Marianne Uhre Jakobsen, Associate Professor, Public Health, Aarhus University, Denmark.

The research to date is based on a strong foundation of animal model studies as well as a growing number of human studies, say these scientists. "Our knowledge of natural trans fats is relatively recent and we will continue to learn more about the human health implications," says Chardigny. "But clearly we know they are different from industrial trans fats and should not be painted with the same brush."

As a leading example, Chardigny presented findings of his meta-analysis of 13 human intervention studies that have examined the impact of natural trans fats on cardiovascular health risk factors. While there is a large body of research confirming detrimental effects of industrial trans fats, the research to date on natural trans fats has revealed no such effects. "There is no association between natural trans fats intake and cholesterol-dependent cardiovascular risk factors," says Chardigny.

This conclusion was further supported by Jakobsen's review of observational epidemiologic studies. "The findings indicate that intake of natural trans fats is not associated with coronary heart disease within the range of intake in the general population."

The scientific knowledge points to the need to clearly differentiate between natural and industrial trans fats on food labels and in health recommendations, say these scientists. At meetings in and around ISSFAL they and colleagues are exploring approaches for further international collaboration among researchers as well as health and food regulatory authorities to make progress on this front.

"We want to help the public better understand the very different health implications of the two different categories of trans fats, including through the nutrition information they get on food labels," says Proctor. "We're confident we can achieve that by continuing to work together."

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#### Low-fat, Low-glycemic And Low-carb Diets Compared

26 Jun 2012 Medical News Today

A low-fat diet may put people at the highest risk for gaining their weight back, because it decreases their resting energy expenditure and total energy expenditure more than other diets, such as a low-glycemic index diet and a very low carbohydrate diet. A team of investigators from Children's Hospital Boston published their preliminary research in JAMA while studying the effects on energy expenditure and components of the metabolic syndrome of these 3 common diets.

A low-fat diet requires a limited amount of fat, most importantly saturated fat, cholesterol, and total caloric intake. This diet typically limits to 1700 calories per day. Foods high in carbohydrates are recommended.

A low-glycemic index diet measures the amount of carbohydrate intake. The diet follows a scale where food is assigned an index number from 1-100 (100 meaning pure glucose). Eating low-glycemic foods take longer for the body to absorb, which makes the person feel satisfaction longer and be less likely to overeat.

A very low carbohydrate diet restricts carbohydrates to about less than 20% of caloric intake per day. Foods containing a higher percentage of proteins and fats are eaten in place of foods such as pasta and bread (foods high in carbohydrates).

#### Dieters struggle to keep the weight off

Many people struggle with weight loss and understand how hard it is to keep the weight off. Unfortunately, these dieters do not know the reasons they put their weight back on and keep trying different diets to find the long-term results they are looking for.

The researchers explain as background information to their report:

"Many people can lose weight for a few months, but most have difficulty maintaining clinically significant weight loss over the long term. According to data from the National Health and Nutrition Examination Survey (1999-2006), only 1 in 6 overweight and obese adults report ever having maintained weight loss of at least 10 percent for 1 year".

The problem is not losing the weight, but keeping it off

#### We lose weight, use less energy, get hungry and put the weight back on

One explanation is that losing weight causes a decline in energy expenditure, while increasing hunger eventually results in weight gain.

In order to evaluate the effects of dietary composition on energy expenditure during weight loss, Carl B. Ebbeling, Ph.D., of Children's Hospital Boston, and colleagues conducted a study using the 3 different weight-loss maintenance diets mentioned above. The study tested the diets on energy expenditure, hormones, and components of the metabolic syndrome between June 2006 sand June 2010.

The study consisted of 21 young adults, either overweight or obese, who achieved 10 percent to 15 percent weight loss while trying a run-in diet. The participants then were chosen one of the 3 diets in random order, each for 4 weeks. The diets were the low-fat diet (high glycemic load), low-glycemic index diet (moderate glycemic load), and very low-carbohydrate diet (low glycemic load). Resting energy expenditure (REE), total energy expenditure (TEE), hormone levels, and metabolic syndrome components were all measured.

There was a significant difference in the energy expenditure during weight-loss in each of the 3 diets. Researchers found that:

- The decrease in REE from pre-weight loss levels was greatest for the low-fat diet (average relative to baseline, -205 kcal/d) while measured by indirect calorimetry in the fasting state.
- The very-low carbohydrate diet showed the least amount of decrease (-138 kcal/d)
- The low-glycemic diet showed intermediate decreases in the low-glycemic index diet.
- Each diet also showed significant decreases in TEE:
  - average -423 kcal/d for low fat
  - average 297 kcal/d for low glycemic index
  - average 97 kcal/d for very low carbohydrate

#### Findings challenged that notion that a calorie is a calorie

The authors said:

"Hormone levels and metabolic syndrome components also varied during weight maintenance by diet (leptin; 24-hour urinary cortisol; indexes of peripheral and hepatic insulin sensitivity; high density lipoprotein [HDL] cholesterol; non-HDL cholesterol; triglycerides; plasminogen activator inhibitor 1; and C-reactive protein), but no consistent favorable pattern emerged.

The results of our study challenge the notion that a calorie is a calorie from a metabolic perspective. TEE differed by approximately 300 kcal/d between these 2 diets [very low-carbohydrate vs. low-fat], an effect corresponding with the amount of energy typically expended in 1 hour of moderate-intensity physical activity.

(Conclusion) These findings suggest that a strategy to reduce glycemic load rather than dietary fat may be advantageous for weight-loss maintenance and cardiovascular disease prevention. Ultimately, successful weight-loss maintenance will require behavioral and environmental interventions to facilitate long-term dietary adherence. But such interventions will be most effective if they promote a dietary pattern that ameliorates the adverse biological changes accompanying weight loss."

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#### Antioxidant-rich tomato paste shows cardio benefits

Two weeks of supplementing the diet with a tomato paste may improve the function of blood vessels in healthy adults, says a new study from Greece.

A daily 70 gram portion of tomato paste containing 33.3 mg of lycopene was associated with a 3.3% improvement in flow-mediated dilation (FMD), a measure of a blood vessel's healthy ability to relax, report researchers from Athens Medical School in the journal Nutrition Research. However, such benefits were only observed after medium term consumption of the tomato product, with no benefits observed over the short term, reported the researchers. "Multiple mechanisms contribute to the effect of tomato products," wrote the authors, led by Panagiotis Xaplanteris.

"The antioxidant properties of carotenoids, mainly lycopene, are central to their beneficial properties. The processing of tomatoes and cooking them with olive oil increases the carotenoid bioavailability. Carotenoids prevent the oxidation of LDL-cholesterol, and some studies report a mild LDL-cholesterol reduction effect after tomato juice supplementation."

#### **Tomatoes beyond lycopene**

The health benefits of tomatoes have been linked to its lycopene content, an antioxidant reported to have heart, blood pressure, prostate, osteoporosis, skin and other benefits in both natural and synthetic form. The Greek researchers explained that they chose to use a whole tomato product and not lycopene in order to directly extrapolate their findings to everyday culinary practices. "The amount of lycopene contained in a serving of tomato paste exceeds the average dietary intake; nonetheless, it represents a physiologically relevant dose that compares favorably to doses used in similar human studies in the past. The beneficial effect of tomato products may be attributed to an additive/synergistic effect of lycopene with other micronutrients, including alphatocopherol, vitamin C, and rutin."

#### Study details

Xaplanteris and his co-workers recruited 19 people with an average age of 39 to participate in their randomized, single-blind, crossover study. Participants continued to consume their regular with or without 70 grams of supplemental tomato paste for two weeks. Results showed that no significant changes in FMD were observed after one day of supplementation, but a 3.3% improvement was observed after 15 days. On the other hand, no supplementation was associated with a 0.5% decline in FMD.

"This is the first study to investigate the endothelial effects of tomato paste administration after a short-term and midterm (1 and 14 days, respectively) period of dietary supplementation in young, healthy volunteers," wrote Xaplanteris and his co-workers. "As hypothesized, tomato paste exerted a beneficial effect on the endothelium as demonstrated by the rise in FMD."

#### Calorie dense, high-fat diet may accelerate cancer development

By Nathan Gray, 22-Jun-2012

#### A high-fat, calorie rich diet could accelerate the development of pancreatic cancer, according to new research in mice.

"Our study showed that a high-fat, high-calorie diet could provide an environmental secondary hit and trigger cancer development," said Dr Guido Eibl from the University of California, Los Angeles – who led the research. "In mice, a diet high in fat and calories led to obesity and metabolic disturbances such as insulin resistance that are seen in obese humans. It also greatly enhanced pancreatic inflammation and pancreatic cancer development," To understand the link between high fat diets and cancer Eibl and his colleagues first tested the hypothesis that diet itself can affect cancer.

They tested this by feeding a corn oil-based diet that had a high content of fat and calories to mice with a genetic mutation that caused them to develop pancreatic pre-cancer. The results showed that 90% of the mice fed the diet became obese, and all of these mice developed insulin resistance and inflammation in the pancreas. Both of these conditions can stimulate the growth of pre-cancerous cells and cancer, said the research team. "This suggests that the high-fat, high-calorie diet accelerated pancreatic cancer development," said Eibl. The researchers are now defining the how such inflammation could be accelerating the development of the cancer – and whether agents such as antidiabetic drugs or omega-3 rich fish oil can halt this disease process.

#### Cereal fibres show prebiotic potential in bread

By Stephen Daniells, 04-Jun-2012, Nutra Ingredients - USA

Bread enriched with specific cereal fibers may beneficially modify bacterial populations in the gut without any adverse effects, says a new study by scientists from the University of Reading, UK and Puratos.

Twenty-one days of consuming arabinoxylan-oligosaccharides-enriched breads boosted bifidobacteria levels in feces and increased fermentation end products such as the short chain fatty acid butyrate, according to findings published in the Nutrition Journal. "AXOS-enriched breads were well tolerated and gave rise to a butyrogenic effect, which is of potential benefit to the consumer," wrote the authors, led by Reading's Gemma Walton. "The effects on fermentation end-products, that were not observed following the placebo breads, indicate that AXOS-bread consumption elicited a potentially beneficial shift in fermentation characteristics." Prebiotics are defined as: "Non-digestible substances that provide a beneficial physiological effect on the host by selectively stimulating the favorable growth or activity of a limited number of indigenous bacteria".

#### **Good news**

Commenting on the study's findings, Prof Glenn Gibson, a leading global prebiotic expert from the University of Reading and co-author of the study, told NutraIngredients-USA: "This study was done to look at an emerging prebiotic (arabinoxylan oligosaccharides) but in an authentic food. namely bread. "The product was very well tolerated. The aim we had was to look at increasing bifidobacteria but it looks like there were ingredients in the non supplemented bread that caused this anyway. We did see increased butyrate in the volunteers stools with the intervention. This was good news, as this is seen to be a very positive microbial metabolite."

#### **Formulation details**

Walton and her co-workers used enzymes called endoxylanases to modify arabinoxylans found naturally in cereal to produce arabinoxylan-oligosaccharides (AXOS) at high levels. Placebo breads were prepared using the same ingredients but no endoxylanases were used. Forty healthy adults were then recruited to participate in a double-blind, placebo controlled human intervention study. Volunteers were randomly assigned to consume 'placebo' breads or test breads containing 2.2 g arabinoxylan-oligosaccharides for 21 days. This was followed by a 21 day 'washout period' before the volunteers were crossed over to the other group.

Results showed that bifidobacteria levels increased following consumption of the AXOS bread, whereas both AXOS and placebo breads were associated with increases in Lactobacilli levels. In addition, the AXOS bread was associated with beneficial shifts in fermentation products like butyrate, and a reduction in compounds associated with protein fermentation, which is "considered to be a non-beneficial process within the colon", said the researchers. Importantly, the researchers also reported no adverse effects on gastrointestinal symptoms for the AXOS-bread.

"In situ enrichment of AXOS in breads provides an enhanced approach to straightforward fortification," explained the researchers. "This process utilises naturally occurring AX – furthermore xylanases are already used within the baking industry. "The production of these breads may be subject to some variations, e.g. as rye and wheat composition may vary amid intrinsic and extrinsic factors. However, providing the level of AX within the grain is in excess of 2%, acceptable levels of AXOS generation would still be possible. "Therefore, it is unlikely that changes in grain will pose a problem in production of AXOS enriched breads."

#### **Dietary Magnesium May Lower Risk of Death from Heart Disease**

By Stephen Daniells, 29-May-2012 Nutra Ingredients – USA

Increased intakes of magnesium in the diet may reduce the risk of cardiovascular mortality by about 50%, suggest new results from Japan.

Data collected over the course of 14.7 years from 58,615 healthy Japanese aged between 40 and 79 indicated similar reductions in the risk of individual cardiovascular events, such as stroke and coronary heart disease. Writing in Atherosclerosis, the researchers state that magnesium's heart benefits are biologically plausible, given a well-reported link between the mineral and improved blood pressure, including a recent meta-analysis in the European Journal of Clinical Nutrition. Magnesium may also benefit heart health by suppressing irregular heartbeats, or by inhibiting inflammation, they added.

#### **Diet**

Dietary sources of magnesium include green, leafy vegetables, meats, starches, grains and nuts, and milk. Earlier dietary surveys show that a large portion of adults does not meet the RDA for magnesium (320 mg per day for women and 420 mg per day for men). Recently, scientists from the Karolinska Institutet in Stockholm, Sweden reported that, data pooled from seven prospective studies revealed that, for every 100 mg per day increase in magnesium intake, the risk of stroke was reduced by about 9% (American Journal of Clinical Nutrition).

#### **Study details**

Using data from the Japan Collaborative Cohort (JACC) Study, the researchers documented 2,690 deaths from cardiovascular disease over the course of almost 15 years, with the highest dietary intakes of magnesium linked to a 50% reduction in the risk of death from

heart disease. When the researchers factored in calcium and potassium weakened the link, but this may be because many of the magnesium-rich foods are also rich sources of calcium and potassium. "It was difficult to determine whether the cardioprotective effects observed in this study were attributed repeatedly to dietary magnesium, calcium or potassium intake," they said. "However, in the present study, reduced mortality from coronary heart disease, heart failure and total cardiovascular disease associated with dietary magnesium intake was maintained after dietary calcium intake was taken into account."

#### Ignore herbal tradition-of-use data and destroy "important heritage": Researchers

By Shane Starling, 05-Jun-2012 Nutra Ingredients

European academics have warned of the likely devastation to the botanicals sector if Europe ignores tradition-of-use (TOU) data in favour of randomised clinical trials when assessing herbal food supplement health claims.

The researchers noted TOU data was acceptable under the 2004 EU Traditional Herbal Medicinal Products Directive (THMPD), but it did not appear it would be accepted under the nutrition and health claims regulation (NHCR). "...the effects observed must be proven under the new health claims rules," wrote the researchers in the European Food and Feed Law Review, led by Robert Anton from the Faculty of Pharmacy at the University of Strasbourg.

"The substantiation required relies mainly on the availability of randomised controlled trials. Evidence from traditional use is not considered. This is bound to lead to the loss of an important heritage. In fact no clear indication about how TOU data will be treated under the NHCR has as yet been given as around 1500 botanical-health claim propositions have been put on hold by the European Commission, as it said the clinical trial-weighted NHCR criteria may not be appropriate for those substances.

#### "...valid scientific discipline..."

But under which criteria they are to be dealt with by the European Food Safety Authority (EFSA) and other EU institutions has not as yet become apparent. "The consideration of traditional evidence from various sources is a valid scientific discipline," they wrote before providing an outline of how to verify and validate herbal TOU data, "as a basis for the assessment leading to the acceptance of health effects for botanicals."

Examples like ginseng, tea, St John's wort and chamomile are given where TOU data has sometimes been validated by clinical data at a later juncture.

#### "Old books often also carry accounts of beneficial effects of plants..."

They recommended that if a claim is fundamentally backed by TOU data, then the claim should reflect that reading something like, "Plant X is traditionally used to contribute to [the physiological function concerned]". "This approach adequately informs the consumer about why the specific food (supplement) in question is being recommended in relation to the labeled health effect."

"The consumer may either accept the traditional basis and use the product or not and abstain from buying/using the product." They added: "Many of the traditionally observed health effects are transmitted orally, but many countries, civilizations and cultures have written accounts, including pharmacopeia (China, India, ...)."

"However, such sources may not always be easily accessible (language barriers, etc), but there is more and more research into these ethnobotanic sources of knowledge making their information more readily available." "Old books often also carry accounts of beneficial effects of plants, used locally in ancient times (Hippocrates, Galen, Paracelsus, ...). The traditional uses described in these ancient sources of information are now increasingly being confirmed by fundamental and applied research."

#### Lactoferrin safe in foods and supplements: EFSA

25-May-2012 Nutra Ingredients

# Milk protein lactoferrin is safe to use in foods and food supplements, the European Food Safety Authority (EFSA) has found after responding to an application from FrieslandCampina.

EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA) said there were no safety issues in a range of matrices including food supplements, infant and follow-on formulae, dietetic food for special medical purposes and sports nutrition, and for foods such as non-alcoholic beverages, cakes and pastries, products derived from cheese, milk-based products, cold snacks and sweets.

After assessing animal and in vitro data, the NDA found no safety issues at proposed intakes ranging from

667mg/100 g for baby foods and foods intended for children aged 1 - 3 years to 4000mg/100 g for energy bars for sportsmen and women. "The toxicological information provided by the applicant included information from an in vitro genotoxicity study, a single dose study, and a four week and a thirteen week oral repeated dose study in rats," the NDA wrote. "The Panel considers that bLF up to the highest dose (2,000mg/kg bw per day) tested in this subchronic rat study did not show adverse effects which could be attributed to the test substance. The Panel concludes that the novel food ingredient bLF (Bovine lactoferrin) is safe under the proposed uses and use levels."

Proposed concentrations of included 100mg/100g for infant formulae; 120mg/100g for non-alcoholic beverages; 125mg/100g for food for special medical purposes; 200mg/100g for dairy product foods intended for children up to 3 years; and 300mg/100g for beverages for sports nutrition. Lactoferrin is an iron-binding glycoprotein and consists of a single polypeptide chain.

#### Leatherhead's 'mega-healthy' meal satisfies health claims

By Rick Pendrous, 11-Jun-2012 Nutra Ingredients

A 'mega-healthy' airline meal has been created by Leatherhead Food Research (LFR), which satisfies all 222 Article 13.1 health claims approved by the European Commission (EC) last month.

Following approval by the EC of this claims list on May 16, LFR chief executive Dr Paul Berryman challenged his team of scientific, regulatory and marketing experts to devise a meal that could make all 222 claims. "It was great fun. I thought of the airline meal concept when flying back from Vitafoods [the functional foods

exhibition] in Geneva," said Berryman. "I had spent three days talking about health claims and at a round table event I suggested that Leatherhead could make a product with all 222 claims, no problem! It wasn't that simple, but we did it within one week!"

It has taken almost five years for scientists on European Food Safety Authority's (EFSA's) Panelon Dietetic Products, Nutrition and Allergies (NDA) to whittle down the 44,000 health claims received from Member States to a final list of 222 general Article 13.1 health claims.

#### Minerals, vitamins

The meal called Leatherhead Airline Meal Formula 222 (see details below) is specially designed for long-haul flights and is packed with minerals, vitamins and everything else that (EFSA) currently thinks is healthy, said Berryman. It even includes charcoal tablets to reduce excessive flatulence – useful in the enclosed airplane cabin – and some sugar-free chewing gum to chew after the meal to freshen breath and neutralise plaque acids, he added.

Chewing also helps relieve pressure in the ears – although he recognised this wasn't an official health claim! For passengers watching their weight, the Leatherhead Airline Meal Formula 222 pack includes mixed berry meal replacement shakes. Jet lag sufferers can also sip on a melatonin-containing hot chocolate drink to relieve their symptoms.

#### 222 health claims

To illustrate the meal, LFR has produced a poster with photos of the airline meal box and each component. It lists all 222 health claims showing which meal component makes which claim. Now that we have the official list of 222 general health claims, Berryman thinks it will be even more important for innovative food companies to establish new scientific evidence for future health claim applications under Article 13.5 or Article 14, which respectively cover claims based on new science, and disease risk reduction and child development claims.

"Our airline formula is just an illustration of what we can do," he said. "LFR is ideally placed to help companies make new claims through regulatory advice, product formulation and our state-of-the art human intervention studies".

Berryman also warned that from December 14 2012, any claims that are not authorised – and not on hold/under consideration – will be prohibited.

#### **Leatherhead Airline Meal Formula 222**

The meal consists of:

- Fresh and smoked salmon terrine with omega-3s alpha-linolenic acid (ALA) and docosahexaenoic acid
- (DHA) for brain and heart function
- ➤ Mixed leaf side salad with extra virgin olive oil dressing for cholesterol claims
- > High fibre multigrain bread roll for 17 claims around fibre, folate and arabinoxylan
- Chicken casserole with lentils and vegetables for iron absorption, vitamins and minerals

- > Live yogurt blancmange for cholesterol, gut health and blood glucose control
- Cranberry, raspberry and elderflower sports drink for energy, vitamins and electrolyte
- Pure spring water to offset dehydration

#### Low carb diets may increase heart disease risk

11-Jun-2012 Food Navigator

Schemes to reduce fat in foods may lead to reductions in heart disease risks, but switching to low carbohydrate foods may lead to increased cholesterol levels and higher risks of heart disease, warn researchers.

The new 25 year study – published in Nutrition Journal – claims to be the first to show that regional and national dietary interventions to reduce fat intake do lead to decreased cholesterol levels, whilst switches to popular low carbohydrate diets are paralleled by in an increase in cholesterol levels. Led by commented Professor Ingegerd Johansson from Umea University, Sweden, the researchers noted that people selected to take part in an intervention programme in northern Sweden decreased reported fat intake over a seven year period from 1986 to 1992.

Fat intake then increased again after 2004, coinciding with widespread media support for low-carbohydrate-high-fat (LCHF) diets, they said. The team reported that whilst the initial intervention – based on better food labelling, improved health information, and cooking demonstrations – reduced levels of cholesterol in the population. The widespread popularity of the LCHF diet several years later was matched with rises in cholesterol levels.

"The decrease and following increase in cholesterol levels occurred simultaneously with the time trends in food selection, whereas a constant increase in BMI remained unaltered," reported Johansson and his colleagues. "These changes in risk factors may have important effects on primary and secondary prevention of cardiovascular disease (CVD)." Johansson commented that while low carbohydrate/high fat diets may help short term weight loss, the results of his current study "demonstrate that long term weight loss is not maintained and that this diet increases blood cholesterol which has a major impact on risk of cardiovascular disease."

#### Probiotics begin to flex their muscle in the sports nutrition market

By Stephen DANIELLS, 21-Jun-2012 Nutra Ingredients

The potential benefits of probiotic ingredients in sports nutrition products may extend beyond immune support, as emerging evidence suggests a potential to enhance protein utilization.

The potential for probiotics for sports nutrition is growing: Data presented by Chris Schmidt from Euromonitor International at the International Probiotics Association's World Congress in Universal City, CA in April indicated that the sports nutrition offers a great opportunity to expand the \$2.7 billion global probiotic supplement market.

Schmidt cited Gaspari Nutrition's Myofusion Probiotic Series as one example of a fast growing consumer brand. The series uses Ganeden Biotech's BC30 strain, and the company sees sports nutrition as a market that is in need of product innovation in several key areas, namely immune and gut health, according to Michael Bush, VP of business development at Ganeden Biotech. Common understanding has it that exercise can suppress the body's immune response in both elite athletes and weekend warriors. There are also reports that nutritional supplementation with products containing large quantities of protein may cause gastrointestinal distress.

#### **Consumer demand**

Daniel Pierce, VP of Brand Strategy & Product Development at Gaspari Nutrition told NutraIngredients-USA that consumer demand will dictate the rise of probiotic-containing sports nutrition products primarily because many sports nutrition supplements serve multiple purposes and immune health awareness is growing. "Fundamentally, if a consumer can purchase a single product that has two functional uses instead of one at a better price point than the two components purchased separately, it's a huge plus. I believe you'll start seeing probiotics included in more and more traditional sports nutrition products such as protein powders, multivitamins, etc because overall health and immune health awareness and performance nutrition are becoming one in the same," said Pierce.

#### The science

Dr. Ralf Jaeger, FISSN, President of Milwaukee-based consultancy Increnovo LLC, told NutraIngredients-USA that the connection between probiotics and immune support is the most obvious application of probiotics in sports nutrition. Certain Probiotic strains

can increase the body's immune response to viruses that cause common viral respiratory tract infections. Improved digestive health through probiotic supplementation might hold the key to other benefits such as improved nutrient absorption.

"While many health professionals believe that probiotics can help people who have specific health conditions, there has been controversy surrounding the benefits of probiotics in healthy people, including athletes, during the last years," said Dr Jaeger. "However, recent studies support the idea that probiotics can indeed benefit those who are healthy. Probiotics have been shown to help support key immune markers upon exposure to cold and flu viruses in healthy volunteers."

#### **Bevond immunity**

Another potential area where probiotics could benefit sports nutrition is in improving protein utilization resulting in strength and lean body increases, said Dr Jaeger. "A recent study indicated that a specific probiotic strain, Ganeden's BC30 increased protein utilization, particular absorption of leucine by 23%," he said.

"Leucine is the most important amino acid to increase post-workout effects on muscle protein synthesis. Combining probiotics with protein might allow athletes to use lower amounts of whey protein without losing the physiological benefit or it will allow athletes with allergies against lactose or who are cautious about cholesterol to use protein sources with naturally lower leucine concentration such as soy and rice."

Dr Jaeger noted that the initial mechanistic studies need to be followed by corresponding efficacy studies, showing the benefits of the probiotic/protein combination on lean body mass and gains in strength. Gaspari's Pierce said he expected the protein utilization developments to lead to more and more probiotics appearing in various protein powders like the Vitamin Shoppe's True Athlete branded products.

In addition, as understanding of the gut-brain axis increases, it is also revealing a possible connection to sports through the potential influence of probiotics on neurotransmitter and hormones, in the context of improving stress response to physical and mental stress, said Dr Jaeger.

#### **Strain specifics**

In addition to the potential of Ganeden's BC30 in this area, there is also evidence that Probiomics Ltd's Lactobacillus fermentum VRI-003 may reduce the days of respiratory symptoms in athletes over a four-month period of winter training (British Journal of Sports Medicine, 2010, Vol. 44, pp. 222-226, and Nutrition Journal, 2010, 10: 30). There is also evidence for Yakult's Lactobacillus casei Shirota strain to reduce the incidence of infection in athletes (Int J Sport Nutr Exerc Metab. 2011, Vol. 21, pp. 55-64), while data from Finland indicated that Lactobacillus rhamnosus GG may shorten the duration of gastrointestinal-symptom episodes, but had no effect on the incidence of respiratory infections in marathon runners (Int J Sport Nutr Exerc Metab. 2007, Vol. 17, pp. 352-363).

#### The Risks of Mixing Drugs & Supplements

## Natural Standard Research Collaboration founder lays out what doctors and patients need to know. By Joanna Cosgrove, Nutraceuticals World June 2012

As a matter of course, physicians routinely ask about the dietary supplements their patients are taking, whether it's to get to the root of a health problem or to avoid a possible interaction with a prescription medication. According to Catherine Ulbricht, PharmD, co-founder of Natural Standard Research Collaboration and senior attending pharmacist at Massachusetts General Hospital (Boston, MA)', asking those questions are critical because while herbal, dietary, and energy or nutritional supplements may offer specific health benefits they can also have harmful and even life-threatening effects when combined with commonly used medications.

In an article published in *Alternative and Complementary Therapies*, Dr. Ulbricht emphasized that clinicians need to be aware of and educate their patients about the potential risks of mixing supplements and therapeutic agents, since their interaction can diminish or increase drug levels. "Natural' does not equal 'safe,'" she said, noting that the effects and interactions of herbal or dietary supplements and functional foods such as energy drinks or nutritional bars can be difficult to predict, especially in younger and older people who have multiple health conditions or take multiple medications. "If something has a therapeutic action in a human body, this substance can also cause a reaction or an interaction."

Common examples include an increased risk of significant bleeding associated with garlic, ginkgo, ginger and saw palmetto supplements; decreased blood sugar as a result of chromium, cinnamon, whey protein and others; hormonal effects of dong quai, black cohosh, kudzu and saw palmetto; and elevated blood pressure caused by bloodroot, green tea, hawthorn and maté.

Dr. Ulbricht said that in order to treat patients safely, physicians would be wise to consider a multidisciplinary approach. "Clinicians are cross-trained to some extent, but cannot be 'jacks of all trades, masters of none,'" she said. Physicians are diagnosticians.

Pharmacists focus on therapeutics. Dietitians focus on diets. Physical therapists focus on exercises. Multidisciplinary teams should be used for patient care. "If a person comes in complaining of symptoms that a clinician cannot quite make sense of and that patient has just started taking new supplements and a new drug, then the clinician can use resources to determine if there is an interaction and document it," she continued. "It is all about communication among providers and between providers and patients. Reporting concerns to product manufacturers is also recommended—whether the manufacturers report these things or not remains to be seen."

If supplement or drug/supplement interactions are suspected, Dr. Ulbricht advocated reporting the interaction, though she lamented the lack of one centralized place for reporting interactions. "Currently, clinicians can file any complaints with the Office of Dietary Supplements (ODS), FDA, Federal Trade Commission (FTC), and Better Business Bureau, as well as many lay sites, including social media sites, blogs, and social health—related sites such as Quackwatch," she said. "The FDA MedWatch reports product recalls. The FTC, National Center for Complementary and Alternative Medicine, or ODS websites also have a button that reads: 'Click here to communicate with us.'"

She went on to say that as reports of interactions accumulate, more integrative/complementary and alternative medicine studies are being indexed in PubMed and MEDLINE, which she said was very important, because these resources are free and internationally-renowned. Dr. Ulbricht stressed that she was not anti-supplement, rather she was pro-caution. "I want to make the point that I do not want to heighten clinicians' fears of using herbs and supplements above over-the-counter or prescription medications," she said. "But I do want to emphasize that herbs and supplements are just as likely to interact and cause side-effects in many cases, so clinicians need to screen their patients for what they are taking and monitor them appropriately."

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## **Food Science & Industry News**

#### Rapidly Cooling Eggs Extends Shelf Life, Cuts Salmonella Risk

June 12, 2012 Food Product Design

WEST LAFAYETTE, Ind.—Rapidly cooling freshly laid eggs extends their shelf-life up to 12 weeks compared to traditional processing, according to a new study published in the journal *Poultry Science*. Previous research also showed the same cooling technology may significantly reduce occurrences of *Salmonella* illnesses. The rapid-cooling process, developed by Kevin Keener, a professor of food science at Purdue University, uses liquid carbon dioxide to stabilize the proteins in egg whites so much that they could be rated AA—the highest grade for eggs—for 12 weeks. Keener said eggs cooled under current methods lose the AA grade in about six weeks.

"There is no statistical difference in quality between eggs as measured by Haugh units [which measure an egg white's protein quality] just after laying and rapidly cooled eggs at 12 weeks," he said. "This rapid-cooling process can provide a significant extension in the shelf life of eggs compared to traditional processing." Results of the study also show the membranes surrounding the eggs' yolks were maintained for 12 weeks when eggs were rapidly cooled. That membrane is a barrier that keeps harmful bacteria from reaching the yolk, a nutrient-rich reservoir that bacteria could use as a food source.

"The structural integrity of the yolk membrane stays strong longer, which may provide a food safety benefit," he said. "The membrane being stronger would be another defense against bacterial invasion, such as salmonella."

The rapid-cooling technology takes liquid carbon dioxide and turns it into a "snow" to rapidly lower the eggs' temperature. Eggs are placed in a cooling chamber and carbon dioxide gas at about minus 110° Fahrenheit is generated. The cold gas is circulated around the eggs and forms a thin layer of ice inside the eggshell. After treatment, the ice layer melts and quickly lowers an egg's internal temperature to below 45° F, the temperature at which Salmonella can no longer grow.

Keener's previous research showed the carbon dioxide in bicarbonate form significantly increases the activity of lysozyme, an enzyme in the egg white that has bactericidal properties. Traditionally, eggs are at more than 100° F when placed into a carton. Thirty dozen eggs are then packed in a case, and 30 cases are stacked onto pallets and placed in refrigerated coolers. The eggs in the middle of the pallet can take up to 142 hours to cool to 45° F, he said.



#### **Diet Goggles Alter Perception of Food**

June 6, 2012 Food Product Design

TOKYO— The secret to dieting may have been unlocked by researchers at the University of Tokyo who developed "diet goggles" that use computer technology and augmented reality to alter the person's perception of food and trick people into thinking they are full or the food they are eating is less appealing. As reported by the *Tokyo Times*, goggle-mounted cameras transmit images to a computer that enlarges the food item a person is eating by up to 50%. Interestingly, the technology allows the person's hand to remain the actual size. The result is the person thinks they are eating a supersized cookie or snack.

In laboratory experiments, study participants consumed about 10% less cookies when they were wearing the diet goggles; they ate 15% more when cookies were made to look smaller than their actual size. The researchers said the technology works "because the brain believes visual information rather than the information it receives from the stomach or our other internal sensors."

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#### Sorry USDA, but more nutrient dense diets do cost more...

By Elaine Watson, 07-Jun-2012 Food Navigator - USA

Just weeks after USDA published a high-profile study posing the question 'Are Healthy Foods Really More Expensive?', researchers in Seattle, Baltimore and the UK have responded with a new study providing the answer: 'Yes'.

In their paper 'Nutrient Intakes Linked to Better Health Outcomes Are Associated with Higher Diet Costs in the US', Adam Drewnowski, Pablo Monsivais and Anju Aggarwal argue that nutrient-rich diets cost more.

Dr Drewnowski, who is director of the Center for Public Health Nutrition at the University of Washington, Seattle, has hit the headlines several times over the past two years after publishing a series of papers highlighting the challenges of meeting the 2010 Dietary Guidelines for Americans , particularly for consumers on low incomes. He has also urged policymakers to take a "reality check" after repeatedly highlighting the disparity between "aspirational" diets and hard reality based on actual eating patterns identified from federal nutrient composition and dietary intake databases.

#### Nutrients associated with a lower risk of chronic disease are associated with higher diet costs

Analysis of dietary intakes in Seattle demonstrated that "nutrients commonly associated with a lower risk of chronic disease were associated with higher diet costs", concluded the authors. "By contrast, nutrients associated with higher disease risk were associated with lower diet costs. The cost variable may help somewhat explain why lower income groups fail to comply with dietary guidelines and have highest rates of diet related chronic disease."

#### Diets higher in sat fats and sugars cost less

The study, published in the peer-reviewed journal *PLoS ONE* on May 25 and funded by a grant from the National Institutes of Health, examined degrees of nutrient intake for every key nutrient in the diet in relation to diet cost and socio economic status. The authors used a sample of data from more than 2,000 adults in the Seattle Obesity Study in which dietary intakes were assessed using food frequency questionnaires. Diet costs for each respondent were then estimated using Seattle supermarket retail prices.

#### Lower cost, lower quality diets more likely to be consumed by lower socioeconomic groups

The results showed that higher intakes of dietary fiber, vitamins A, C, D, E, and B12, beta carotene, folate, iron, calcium, potassium, and magnesium were associated with higher diet costs, with the cost gradient most pronounced for vitamin C, beta carotene, potassium, and magnesium. Conversely, higher intakes of saturated fats, trans fats and added sugars were associated with lower diet costs, said the authors.

"Lower cost, lower quality diets were more likely to be consumed by lower socioeconomic groups... The cost gradient might help explain why lower income groups have least nutrient adequate diets and are at higher risk for chronic disease including obesity and diabetes."

#### Potassium and vitamin C a particular challenge

People in the highest quintile of intakes for saturated fats, trans fats and added sugar had significantly lower diet costs, as compared to those in the lowest intake quintiles, added the authors. "Based on current eating habits, compliance with dietary guidelines is likely to entail higher diet costs for the consumer." However, not all beneficial nutrients are equally expensive, they noted. "The most pronounced positive gradient with diet cost was seen for vitamin C, beta carotene, potassium and magnesium – nutrients primarily obtained from fruits and vegetables. By contrast, calcium and vitamin D showed a weaker association with diet cost, likely because milk and milk products are relatively inexpensive. Iron and folate also showed a weak association with diet cost, which may reflect the ubiquity and relatively low cost of grain products fortified with iron and folate. There is clearly a need to identify and promote inexpensive food sources of key nutrients in order to improve the dietary quality of lower socioeconomic status groups."

#### More research needed to identify cheaper ways of promoting beneficial nutrients to consumers

While food frequency questionnaires have certain known biases, they are a useful tool to make comparisons across subjects, they noted. "Nonetheless, the present findings have implications for future research. First, diet cost variable ought to be taken into account in future studies on diets and disease risk. "Second, further research is needed to identify cheaper ways of promoting beneficial nutrients to the consumer, particularly among lower income and lower education groups."

#### Indian nutraceutical market booming

By Ankush Chibber, 18-Jun-2012 Food Navigator – Asia

India's nutraceutical market is booming, but food manufacturers will have to pay heed to growing trends of fortification and customisation to truly unlock the value, a white paper has said.

According to Frost & Sullivan, the market was worth US\$1.48bn in 2011 and would grow to US\$2.73bn in 2016, at an annual rate of 13%. The report revealed that dietary supplements are the largest category accounting for 64% of the nutraceuticals market, driven primarily by vitamin and mineral supplements.

Functional foods will be the quickest growing category until 2015 followed by dietary supplements. However, dietary supplements, specifically herbal and dietetic supplements, have the most potential for nutraceutical manufacturers, driven by growing demand from an evolving consumer base.

#### **Growing health concerns**

Several factors support India's market. For example, between 1998 and 2005, India's overweight rates increased by 20% so that 13% of women and 9% of men in the 15-49 age groups are overweight or obese. India has become the diabetic capital of the world with 55 million diabetics in 2010. Of all deaths in the last decade, 40% have been cardiovascular related. The number is expected to cross the 50% mark by 2020, the report said.

#### Fortification is the way to go

According to the report Indian consumers have shown a preference for instant mixes and fortified foods, over tablets and tonics. Gayathry Ramachandran, Senior Consulting Analyst, Chemicals, Materials & Foods Practice, Frost & Sullivan - South Asia, Middle East and North Africa, told FoodNavigator-Asia that the latter are closely linked in the consumer' mind to sickness and disease.

"We found that Indian consumers preferred that they get their required nutrition in their day-to-day food. They also want to camouflage the taste of such supplements with their regular food," she said. Ramachandran added that the ease and speed of preparation of instant mixes make them more usable.

"We are now seeing breakfast cereals fortified with iron, malted fortified with Vitamin D and beverages fortified with minerals and vitamins," she added.

#### **Customisation kudos**

Ramachandran said group discussions with consumers revealed Indian consumers tended to customise the available nutraceutical products to their needs. "Consumers told us that they would not mix their powder supplements in water but rather with other flavor mixes to increase the taste profile of those supplements," she relayed. Flavour masking and flavour enhancing techniques were also on the rise. "One big example of this has been the development of omega-3, a traditionally non-vegetarian product, with vegetarian variants, thereby allowing it to gain traction with the large Indian vegetarian population."

#### Lack of framework hurting manufacturers

Ramachandran said a lack of regulatory frameworks and standards for nutraceuticals has led most manufacturers to target export markets and use those standards in India. The Food Safety and Standards Authority of India (FSSAI) has circulated a draft regulation on standards for nutraceuticals and supplements but it has been pending for more than a year. Ramachandran added that this is one of the reasons why India's nutraceutical market is in a state of oligopoly, with the market being dominated by big pharma and large FMCG firms. "With no clear framework and standards to work towards, smaller companies are unable to spot a clear opportunity for themselves, favouring the export market instead," she added.



#### Researchers develop new beta glucan-rich oats

By Caroline Scott-Thomas, 18-May-2012 Food Navigator - USA

Researchers at the University of Wisconsin claim to have developed a new oat variety that is richer in beta glucan, a compound that has been linked to heart health.

Program manager of the Small Grains Breeding Program in the UW-Madison agronomy department, John Mochon, said that the BetaGene oats are 2% higher in beta glucan than regular oats — which would lead to 20% higher levels of beta glucan in products made with the oats. The Food and Drug Administration has approved a health claim for soluble fiber from whole oats and a reduced risk of heart disease, and oat beta glucan has also been given the health claim thumbs-up in Canada and the European Union.

Mochon said that although Wisconsin is one of the United States' top producers of oats, oat harvests across the nation have been in steady decline, as farmers have looked to other crops with better returns. "That's why I'm trying to add value to oats. It's one of my goals to reverse that trend," he said. "Things like increased beta glucan, developing forage lines, developing lines that are rust resistant, and developing lines that have a high groat percentage are all part of this effort."

UW breeders are hoping to release the new variety for the 2014 growing season. It has taken them 14 years of cross breeding and field trials to bring the oats to this point. "The biggest thing that stands out about this new variety, BetaGene, is that it's both a high yielding variety and high in beta glucan," Mochon said. He claims that the industry has already shown interest in the oat variety, and one large miller recently visited Wisconsin to learn more about the ingredient. He also claims that it could also have international potential, particularly in Canada, as a major oat-producing nation.



## **Regulatory News**

#### **Disney Rewinds Standards for Food Advertising to Kids**

June 5, 2012 Food Product Design

BURBANK, Calif.—The house the mouse built is literally changing the way it does business to help U.S. children lead healthier lives. The Walt Disney Company today introduced new standards for food advertising on programming targeting kids and families that encourages more fruit and vegetable consumption, limits calories and reduces saturated fat, sodium and sugar.

The new initiative builds on the company's 2006 landmark nutrition guidelines that stipulated promotions aimed at children 12 years old and under—most notably for films—would feature only healthier food and beverage products.

Under Disney's new standards, all food and beverage products advertised, sponsored or promoted on Disney Channel, Disney XD, Disney Junior, Radio Disney and Disney-owned online destinations oriented to families with younger children will be required by 2015 to meet Disney's nutrition guidelines that are aligned to federal standards, promote fruit and vegetable consumption and call for limiting calories and reducing saturated fat, sodium and sugar.

"We're proud of the impact we've had over the last six years," said Robert A. Iger, Chairman and CEO, The Walt Disney Company. "We've taken steps across our company to support better choices for families, and now we're taking the next important step forward by setting new food advertising standards for kids. The emotional connection kids have to our characters and stories gives us a unique opportunity to continue to inspire and encourage them to lead healthier lives."

Disney also unveiled its "Mickey Check" tool, an icon that calls out nutritious food and menu items sold in stores, online, and at restaurants and food venues at its U.S. parks and resorts. By the end of 2012 the "Mickey Check" will appear on licensed foods products, on qualified recipes on Disney.com and Family.com, and on menus and select products at Disney's Parks and Resorts.

Also in 2006, Disney pioneered new, well-balanced kids' meals served at its Parks and Resorts that automatically include nutritious sides and beverages, such as carrots and low-fat milk, unless parents opt out. Of the more than 12 million kids' meals served last year at Disney Parks and Resorts in the U.S., parents stuck with the healthier options 6 out of 10 times. Now, Disney will enhance its breakthrough efforts by further reducing sodium in kids' meals and introducing new well-balanced kids' breakfast meals.



#### **Scientists Create Antimicrobials That Kill Disease-Causing Pathogens**

June 26, 2012 Food Product Design

BELTSVILLE, Md.—U.S. Department of Agriculture (USDA) scientists have developed a new method to create antimicrobials that kill disease-causing pathogens, which in turn, can be used as an alternative to antibiotics.

Growing concerns about antibiotic resistance to certain strains of bacteria and increasing restrictions on the use of antibiotics in animals has accelerated the need to find alternatives. Scientists with the Agricultural Research Service (ARS) are working to provide new strategies for enhancing production and improving overall animal health. The research supports the USDA priority of promoting international food security.

The patented technology for designing pathogen-targeted antimicrobials is the work of molecular biologist David Donovan at the ARS Henry A. Wallace Beltsville Agricultural Research Center (BARC).

Viruses that infect bacteria, called bacteriophages (phages), produce enzymes that can be used to kill pathogens. These novel enzymes have been shown to be effective in killing pathogens like *streptococci* and methicillin-resistant *Staphylococcus aureus* (MRSA).

Collaborating with industry, university and federal scientists, Donovan demonstrated that these particular enzymes have molecular domains that can be isolated and will act independently of their protein surroundings. They kill bacteria by eating or chewing up the walls of cells. The enzymes can be manipulated to create an antimicrobial that targets and kills only specific pathogens, which greatly reduces the probability that non-targeted bacteria will develop resistance.

"These enzymes—known as 'endolysins'—have molecular domains that can be isolated and will act independently of their protein surroundings," Donovan said. "They can be shuffled like cars in a train, resulting in an antimicrobial that targets just the pathogens of interest, significantly reducing the odds that non-targeted bacteria will develop resistance."

In other research, compounds proven to be effective in killing foodborne bacteria may hold potential for treating piglets and calves.

Microbiologist Robin Anderson and his colleagues at ARS's Food and Feed Safety Research Unit in College Station, Texas, received a patent for their invention, which provides a method for controlling foodborne intestinal bacterial pathogens in animals. Chlorate and a certain class of chemicals called "nitro compounds" were shown to substantially reduce or eliminate the important foodborne pathogens *Salmonella* and *Escherichia coli* O157:H7.

Antibiotics are currently used to treat mastitis, the most costly and common disease of dairy cattle. But an alternative treatment may soon be available. Scientists at the ARS National Animal Disease Center (NADC) in Ames, Iowa, have found that a natural remedy—vitamin D—can delay and reduce the severity of mastitis infection in dairy cattle.

In other research, ARS scientists have demonstrated the effectiveness of using food supplements and probiotics, molecules produced by cells of the immune system, and phytonutrients to fight poultry diseases like coccidiosis. They are now applying similar technology to develop alternatives to treat enteric (intestinal) bacterial infections caused by *Clostridium*, a pathogen associated with necrotic enteritis in poultry.

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#### Who says the FDA doesn't listen? Industry welcomes plan to issue revised draft NDI guidance

By Elaine Watson, 20-Jun-2012 Nutra Ingredients – USA

The FDA might have spent the past year vigorously defending its much-maligned draft guidance on new dietary ingredients (NDIs), but it appears it has been listening to industry concerns as well.

Indeed, it has taken them so seriously that bosses now plan to ditch the offending document, and replace it with a second, revised, draft. While FDA supplements division chief Dr Dan Fabricant certainly gave no hints he was considering such a step during recent public appearances, trade associations had described him as "engaged" and "receptive" during recent meetings where they voiced their concerns.

#### **Fabricant:**

Revised draft will 'address points that may need further clarity to avoid misinterpretation, and possibly being taken out of statutory context'

The news was communicated following a meeting yesterday between the offices of Senators Orrin Hatch (R-Utah) and Tom Harkin (D-Iowa) and FDA commissioner Margaret Hamburg, deputy commissioner Michael Taylor and assistant commissioner Jeanne Ireland. In a note sent to trade associations after the meeting, Dr Fabricant said: "We are planning on promulgating a revised draft NDI guidance to address points that may need further clarity to avoid misinterpretation, and possibly being taken out of statutory context."Please assure your members that the comments received in December are still being administratively reviewed and vetted accordingly."

#### **CRN: A good outcome**

Council for Responsible Nutrition (CRN) chief executive Steve Mister told NutraIngredients-USA this was good news for the trade: "The FDA has acknowledged we have some valid concerns, and plans to address all five of the substantive issues we raised in our comments."Not only did all the legal comments resonate, but also some of the political pressure I think has had an effect."

As to how unusual it was for the FDA to issue revised draft guidance (which will be subject to public comment - again) instead of final guidance, Mister said: "It's hard to say. Some pieces of guidance just sit around as a draft for years, others move faster. The important thing is that this is a good outcome." The FDA had not said when it plans to issue the revised draft, he said. "But one thing we do know is that in the next few weeks the FDA will be talking to us all about industry lists of grandfathered [pre-1994] dietary ingredients."

#### **UNPA:**

Is an NDI a single substance or a finished product?

United Natural Products Alliance (UNPA) executive director Loren Israelsen said UNPA was "pleased by the clear progress made at yesterday's meeting" and understood that the "discussion was both cordial and specific" with respect to industry concerns. He added: "Of particular concern is the definition of a New Dietary Ingredient, whether this is a single substance or a finished product. "We are advised that this issue was discussed in some detail and will be addressed as a central point. No timetable has yet been laid out for this next phase."

#### AHPA:

This is deeply gratifying

American Herbal Products Association (AHPA) president Michael McGuffin said it was "deeply gratifying to hear that FDA has decided to rethink its approach to good guidance on this important element of DSHEA (Dietary Supplement Health and Education Act, 1994)". Dr Cara Welch, Vice President, Scientific & Regulatory Affairs at the Natural Products Association said the FDA's "decision to issue a second draft for comment as opposed to a final guidance reflects the serious concerns indicated in industry's comments and the agency's desire to get it right".

The Alliance for Natural Health USA, which has conducted a high-profile campaign to get the FDA to reconsider its approach to the guidance, also welcomed the move. Campaigns and communications director Darrel Rogers told NutraIngredients-USA: "The ANH-USA and a small group of supplement companies recently decided to pursue FDA's House appropriators and worked with the Republican Sub-committee chair Jack Kingston and ranking Democrat Sam Farr to include NDI withdrawal language in a report that accompanies FDA's budget that was reported out of their committee last week. In addition to the sustained efforts of Sens. Hatch and Harkin we believe that the House appropriators report language really contributed to getting FDA back to the negotiating table."

#### **Emord:**

This is a partial victory, at best

However, Virginia-based food law attorney Jonathan Emord said this was "a partial vistory at best" for the trade. He added: "The draft guidance revealed the worst in agency statutory construction, interpreting the NDI section to mean the opposite of its plain and intended meaning. The interest in revision is a partial victory, at best. The guidance should be withdrawn. "The agency should respect the need to defer to Congress on fundamental changes to the NDI provision. FDA occasionally changes its Guidance documents in response to public comments, Court orders, or pressure from Congress, but substantial changes are rare."

#### Unworkable and unfair

Under DSHEA, firms are required to notify the FDA if they intend to market a dietary supplement in the US that contains a 'new dietary ingredient' (which has not been marketed in the US dietary supplements market before October 15, 1994) and demonstrate that it is safe. Although the industry had been asking for guidance on NDIs since DSHEA was passed in 1994, the document the FDA finally produced 17 years later in July 2011 was roundly slammed by the trade as unworkable, unfair, and inconsistent with the legislation it was designed to clarify.

The CRN understands that the agency will revisit the five specific areas of concern that all of the industry's trade associations highlighted as particularly problematic. These include:

- Industry responsibility for proving grandfathered status of particular ingredients;
- The permissibility of using synthetic versions of botanical components in supplements;
- > The definition of the term "chemically altered";
- NDI submissions for an ingredient versus finished products; and
- ➤ The level of data necessary to demonstrate the safety of NDIs.

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#### Judge delivers more bad news for FTC on 'two clinical trials' standard

By Elaine Watson, 21-Jun-2012 Nutra Ingredients – USA

Further evidence that 'competent and reliable scientific evidence' to support claims on dietary supplements does not have to mean two well-controlled human intervention trials has emerged in a ruling in a federal court in Florida.

Judge Donald M Middlebrooks was asked by the Federal Trade Commission (FTC) to modify a consent decree from 2006 that was designed to bring the FTC's false advertising dispute with supplement maker Garden of Life (GOL) to an end. Although Garden of Life had signed the decree, it had continued to make unsubstantiated and deceptive claims about its products, despite agreeing not to "make representations... without possessing competent and reliable scientific evidence substantiating" them, claimed the FTC. To tackle the problem, the ad watchdog wanted a judge to modify the decree by re-defining "competent and reliable scientific evidence" to mean "two adequate and well-controlled human clinical studies".

#### Judge: Sort it out between yourselves

But Middlebrooks was not persuaded. In a May 25 ruling, he said it was not for him to decide whether GOL's health claims were deceptive, only whether the FTC had the right to retrospectively alter the definitions to which it had already agreed in the 2006 consent decree. He added: "While what qualifies as competent and reliable scientific evidence... may be subject to debate, the fact remains that the parties themselves agreed to use that definition after engaging in extensive negotiations...

"The FTC failed to establish that a significant change in factual circumstances occurred since the date the Parties entered into their agreement. "Thus, this Court lacks the authority to impose additional restrictions upon GOL, and, it is hereby ordered and adjudged that Plaintiff's [FTC's] motion ... is denied."

#### Attorney: The Court rejected the FTC's position

Writing about the case in the FDA law blog, Hyman, Phelps & McNamara attorney Riëtte van Laack said: "The FTC's proposed modifications sought to redefine competent and reliable scientific evidence to mean two adequate and well-controlled human clinical studies for claims regarding bone and cognitive health benefits of GOL's products and FDA approval for disease treatment and cure claims for GOL's products.

"The Court rejected the FTC's position. "In 2006, FTC and GOL agreed to use the more vague definition of 'competent and reliable scientific evidence' and the Court found that the FTC could have anticipated that experts might disagree. "The Court ruled that the FTC cannot now, five years later, merely because it is no longer satisfied with the negotiated definition, have the Court modify this definition to suit the FTC's purpose."

#### **POM Wonderful ruling**

Middlebrooks' decision follows a high profile ruling by administrative law judge Michael Chappell in the false advertising dispute between the FTC and POM Wonderful over evidence required to support claims about the health benefits of pomegranate juice. While Chappell argued that many of POM's claims did not hold up to scrutiny, he challenged the notion that 'competent and reliable scientific evidence' has to mean at least two 'gold standard' human trials.

Indeed, so-called 'gold-standard', randomized, double-blind placebo-controlled human clinical trials (RCTs) are not essential for supporting structure-function claims on foods and supplements and are "not necessarily" even essential for products marketed as reducing the risk of disease, argued Chappell.

#### **Garden of Life**

According to the FDA, GOL continued to make unsubstantiated advertising claims that its Primal Defense, RM-10, Living Multi, and FYI supplements could treat immune disorders, cancer, diabetes and rheumatoid arthritis respectively. Founded in 2000, West Palm Beach, Florida-based Garden of Life markets a range of supplements from digestive health product Perfect Cleanse and probiotic supplement Primal Defense to its fücoTHIN weight management range.

