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Weight management surprise win in EU health claims lottery

By Julian Mellentin

Companies have become accustomed to the European Food Safety Authority (EFSA) almost routinely rejecting proposed health claims. Certainly the most recent batch of health claim opinions – published on 19th October – maintains EFSA's tradition of a 90% rejection rate. However, although it's not often that something good comes out of the EU's health claims process, on this occasion – incredibly – there might be something positive to say.

Buried in the EFSA dung-heap is a nugget of gold that may help product developers who have the imagination and creativity to do something with it. The nugget is EFSA's unexpected, first-ever approval of a weight-management claim for a specific food ingredient.

The ingredient approved is glucomannan, better known as konjac fibre. The EFSA review panel concluded that it agreed that a cause and effect relationship has been established between the consumption of glucomannan and the reduction of body weight and it authorised the proposed health claim:

Glucomannan contributes to the reduction of body weight in the context of an energy-restricted diet.

Many companies that have been experimenting with weight management products – such as those based on fibre and proteins for satiety, which are now not approved by EFSA to make a satiety claim – suddenly are faced with a unique opportunity to do something in weight management with a claim that's EFSA-approved.

It's worth noting that when the cholesterol-lowering brands such as Benecol, Danacol and Becel got EFSA's approval for their health claims, marketers began using terms such as "EU approved" in print and radio advertising – and in many markets sales went up markedly.

An American brand called NeuroTrim is one of the few brands in Europe already offering a weight management benefit based on the presence of konjac.

Not only does konjac now have a unique claim, the clinical evidence is that it actually works, so enabling consumers to "feel the benefit" – something now well-established as a key success factor in the business of food and health.

Konjac fibre will be unfamiliar to many product developers, but it is already used in many foods as a gel or thickener (it's described as E425 on many product labels). It's a soluble fibre derived from the root of the konjac plant – enabling marketers to communicate a "natural plant extract" message of the kind that has already worked well for many ingredients.

Konjac forms a viscous, gel-like mass in the stomach when hydrated and this is clinically proven – certainly to the satisfaction of EFSA's near-pharmaceutical standards of clinical proof – to induce a sense of satiety leading to a decrease in subsequent energy intake. In order to obtain the claimed effect, 3g of glucomannan should be consumed daily.

"I believe the EFSA decision will help enormously to put konjac in a better light," says Ross Campbell of CyberColloids, a company which provides expert help with innovation for companies using and making hydrocolloids. He adds: "It will certainly encourage food formulation work and I think

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Science gives beetroot brand a superfood boost

A start-up brand has embraced the science of sports nutrition and blood pressure-lowering and is spearheading the reinvention of beetroot as a superfood. By Julian Mellentin.

James White Drinks' development of its innovative juice drinks is a text-book example of how to commercialise nutrition science. Central to its strategy is marketing the intrinsic health benefits of the humble beetroot. The company has begun with a focus on supplying elite athletes, coupled with distribution through health food stores, with a convenient "concentrated dose" package. Meanwhile, it's deepening its collaboration with scientific researchers to put in place the science that can justify an approved health claim, and it's looking for partnerships to roll-out the concepts internationally.

The benefits of the company's Beet It brand are based on beetroot's naturally high nitrate content. On the face of it, nitrates might seem like an unlikely starting point for a health brand. Commonly used as a preservative in processed meats – as well as occurring naturally in high concentrations in vegetables – from the 1950s nitrates were treated as a potential risk factor for colon cancer when researchers found a link between nitrates and cancer in laboratory rats.

Public health officials adopted the premise that nitrates are detrimental to human health and regulations were introduced in Europe, the US and elsewhere limiting the permitted levels of nitrates found in drinking water, for example, as well as in foods.

There was just one problem – the slur against nitrates was based solely on an extrapolation from the rat studies of the 1950s, and in fact epidemiological studies have never found any association between nitrate intake and disease in humans[1].

In fact, far from finding that nitrates had the potential to be harmful, researchers began to suspect that dietary nitrate might play a significant role in supporting human health. As far back as 1994 researchers at the prestigious Karolinska Institute in Stockholm and at the Peninsula Medical School at the University of Exeter, UK, independently observed that the human stomach contains the gas nitric oxide (NO). The question was where the gas was coming from. Nitric oxide performs several vital functions in the body, including dilating blood vessels, and for these activities, a cellular enzyme called nitric oxide synthase extracts the gas molecule from arginine, an amino acid. Chemists have long known another mechanism: at low pH, nitrite forms a stew of nitrogen-oxygen compounds, including nitric oxide. Bacteria in the mouth convert nitrate to nitrite, which gets swallowed, so the stomach can naturally produce nitric oxide. If nitric oxide were truly beneficial to the stomach, harmless bacteria feeding on nitrate-rich saliva might have a symbiotic relationship with humans.

To test this idea, researchers exposed bacteria responsible for stomach infections to stomach acid both alone and mixed with nitrite. Although acid is often thought to be the stomach's main line of defense against invading bugs, the researchers found that E. coli, Salmonella and other bacteria could survive for hours in it, whereas high normal concentrations of nitrite plus acid killed the bacteria in less than an hour.

Researchers in Japan, the US and elsewhere also worked on nitrates and found that they lowered diastolic blood pressure, with no effects on systolic blood pressure. Interestingly, the effects were found in people with seemingly normal blood pressure.

The turning point can be said to have come in 2008, when a research team headed by Amrita Ahluwalia, Professor of Vascular Biology, Center for Clinical Pharmacology, William Harvey Research Institute, Queen Mary University of London, found that consumption of beetroot juice exerted a number of beneficial effects, including lowering of both systolic and diastolic blood pressure. The study – funded by the British Heart Foundation - was published in the American Heart Association journal, *Hypertension*.

At that stage the research team was uncertain whether the beneficial

cardiovascular effects of beetroot juice were specifically attributable to the dietary nitrate content of beetroot, but studies since then (see box) appear to have cleared up that question, affirming the role of beetroot's high content of dietary nitrate, which converts into usable nitrate or nitric oxide in the body.

It's not only blood pressure lowering that is in the spotlight. Researchers at Exeter University Medical School, specializing in sports nutrition, have also found sports performance benefits from consumption of beetroot juice (see box).

It's a long way from the world of cutting-edge scientific research to a small juice company, but James White's lucky break came because back in 2008 it was the only company marketing a beetroot juice in the UK and it began supplying its juice to researchers to use in clinical studies.

When the Ahluwahlia study was published, the company told *New Nutrition Business* back in 2008, sales of its regular beetroot juice grew five-fold in the wake of the publicity. To capitalize on the emerging benefits the company began marketing Heart Beet, an organic beetroot juice, retailing in 250ml bottles and sold through health food stores.

"I'm not a scientist so I'm new to this," comments Lawrence Mallinson, CEO and founder of James White Drinks. A serial entrepreneur, he was previously one of the founders of the New Covent Garden Soup Company, today the second-biggest soup brand in the UK after Heinz.

"Products with the highest quality ingredients and the best taste are where my marketing experience has been - this world of claims is new to me. Suddenly I find myself in areas where we're talking about drinking juice because it reduces blood pressure or improves sporting effort."

While many small companies shy away from the science Mallinson recognized that his company – whose core business is pressed apple juice – needed to embrace it and the company has followed the research closely. Today the company co-owns patents relating to the effect of beetroot juice jointly with individual researchers at the Karolinska Institute.

ELITE ATHLETE FOCUS FOR LAUNCH

The company has meanwhile re-positioned Heart Beet as Beet It, a name that is intended to also embrace the sports market opportunity.

In the world of elite athletes there is a never-ending quest for products that will boost performance and word got around among sports nutritionists at the professional level about the research at Exeter University.

"We're now supplying international rugby teams, premiership football teams and athletes. Word of mouth has been very powerful," observes Mallinson.

Beetrot juice has a polarising taste, adds Mallinson: "About a third of people love it and two thirds find it difficult. To try and get past the taste barrier we said to the sports people that we were thinking about concentrating it, to enable people to down a dose without having to drink a full 250ml bottle."

The response was positive, so the company launched a 70ml shot version, which contains 5mmol of nitrates, the same as found in 250ml of beetroot juice, called Beet It Concentrated Organic Beetroot Stamina Shot.

"All the sports people have gone to it," explains Mallinson. "It's a more intense, slightly thicker drink. The 250ml juice smells and tastes exactly like beetroot, but the Stamina Shot doesn't have the smell of beetroot or the taste. When you concentrate it, it becomes very sweet. But people drink it not as a drink but for its functional properties."

"Beetroot isn't an easy product to handle," observes Mallinson, whose company has had to develop know-how in processing the vegetable. "We are really apple pressers and apple is acidic, stable and easy to handle. Beetroot is alkali so naturally the difficulty comes with adjusting acidity level."

The Stamina Shot is hot-filled and shelf-stable and so it needs no added preservatives but still has a shelf-life of 10 months.

"It's the world's first organic shot with no preservatives," says Mallinson. "Organic is a positioning – when you are marketing to a medically interested audience it's a positive."

Stamina Shot also carries the logo of Informed Sports, an organization that tests products to provide assurance that sportspeople will not fail drugs tests as a result of using them.

EXPANDING DISTRIBUTION CAREFULLY

Mallinson is refreshingly frank that the company's product is several months behind schedule as a result of challenges with processing equipment, but Stamina Shot is soon to join the 250ml drink in Holland and Barrett, the UK's largest health food store chain with over 200 stores, and is being distributed to the wider health food store trade and will shortly go into GNCs.

The price is, typically for shots, super-premium at £1.79 ($2.85/€2.05) for a 70ml bottle, equivalent to around £25.50 ($40.60/€29.25) per litre. By comparison, the 250ml Beet It sells for around £1.49 per bottle ($2.38/€1.70), equivalent to most smoothie brands.

Expanding distribution is being taken one step at a time. "We are historically a fine foods company and I never thought we would be doing anything like this so we're making sure we get it right every step of the way," says Mallinson. "We began with elite athletes and now we are in health food and later we'll look at supermarket distribution. We've already had some conversations with supermarkets but they're not sure where to place shots in their stores – they're having some difficulty with them.

"For now we're focusing on a heartland of people – serious and aspiring sports people and people serious about exercise and who

need to get the best from their bodies – we've even found ballet dancers using out product."

HEALTH CLAIM AIM

The European Union's exacting health claims regime does not deter Mallinson. "We can see where the research is headed and we can see what the standards are that EFSA is looking for. A lot of claims have been rejected because they didn't characterize the active ingredient sufficiently. That's not a problem we'll have with beetroot juice."

"We're steadily building up a dossier for the shot – because with that we've got something that no-one else has."

The next step is international distribution – the company has already shipped its first order to in Australia. "We're a small company so we need partners and licencees," observes Mallinson. "For the right people the potential of beetroot juice will be huge."

Reference:
1. Dietary nitrate in man: friend or foe? Knight, Duncan, Leifert and Golden, British Journal of Nutrition (1999), 81, 349-358

BEETROOT'S GROWING SUPPORT IN SCIENCE

1. SPORTS NUTRITION

A study conducted at the University of Exeter and published in May 2010 in the *Journal of Applied Physiology* found that drinking beetroot juice reduces the energy expended by muscles.

The research builds on a previous study (also published in the Journal of Applied Physiology), which showed for the first time that drinking beetroot juice can boost stamina, allowing an individual to exercise for up to 16% longer. The authors suspected that this was connected to the very high nitrate content of beetroot juice turning into nitric oxide in the body, leading to a reduction in oxygen uptake. The latest study confirmed that initial finding and also described the processes in the muscles that make exercise less tiring.

In the study healthy men completed a series of knee extension exercises, which work the quadriceps muscles in the thigh. The level of exertion was assessed using an ergometer. An MRI scanner enabled the researchers to record the internal processes of the muscle. In addition, the volunteers' oxygen uptake was monitored. The exercises were repeated several times, sometimes after the volunteers had drunk half a litre of organic beetroot juice a day over six days and sometimes after they had drunk a placebo of blackcurrant cordial.

Drinking beetroot juice doubled the amount of nitrate in the blood of the volunteers and reduced the rate of utilization of adenosine triphosphate (ATP), the most immediate source of energy for muscles. This suggests that drinking beetroot juice enables muscles to complete the same work more efficiently. Furthermore, after drinking beetroot juice, oxygen uptake was reduced during both low-intensity and high-intensity exercise.

Corresponding author of the study, Professor Andy Jones of the University of Exeter's School of Sport and Health Sciences, said: "We continue to be impressed by the physiological effects of increasing dietary nitrate consumption. While our previous research demonstrated the benefits of nitrate-rich beetroot juice on stamina, our latest work indicates that this is consequent to a reduced energy cost of muscle force production.

"Since our first study came out we have seen growing interest in the benefits of drinking beetroot juice in the world of professional sport and I expect this study to attract even more attention from athletes."

2. BLOOD PRESSURE

A study published in June 2010 the American Heart Association journal *Hypertension*, found that blood pressure was lowered within 24 hours both in people who took nitrate tablets, and people who drank beetroot juice. The researchers affirmed that the nitrate content of beetroot juice is the underlying cause of its blood pressure lowering benefits.

Study author Amrita Ahluwalia, Professor of Vascular Biology at London-based Queen Mary's William Harvey Research Institute, said the investigation was able to demonstrate that the nitrate found in beetroot juice was the cause of its beneficial effects upon cardiovascular health by increasing the levels of the gas nitric oxide in the circulation.

Professor Ahluwalia said: "We gave inorganic nitrate capsules or beetroot juice to healthy volunteers and compared their blood pressure responses and the biochemical changes occurring in the circulation.

"We showed that beetroot and nitrate capsules are equally effective in lowering blood pressure indicating that it is the nitrate content of beetroot juice that underlies its potential to reduce blood pressure. We also found that only a small amount of juice is needed – just 250ml - to have this effect, and that the higher the blood pressure at the start of the study the greater the decrease caused by the nitrate.

Our previous study two years ago found that drinking beetroot juice lowered blood pressure; now we know how it works."
"Inorganic Nitrate Supplementation Lowers Blood Pressure in Humans", by Kapil et al. was published in the AHA journal *Hypertension* on Monday 28 June 2010.