

DISPATCHES FROM THE NCA STATE OF THE INDUSTRY CONFERENCE IN MIAMI

## US cocoa flavanol health claim nears but 'not quite there yet'

By Oliver Nieburg+, 10-Mar-2014

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### More clinical trials are needed for a US health claim on cocoa flavanols, according to the National Confectioners' Association's technical director.

Speaking to ConfectioneryNews at the NCA's State of the Industry Conference in Miami, Laura Shumow, director of technical and regulatory affairs at the NCA said: *"There's quite a rigorous body of evidence that is required to get a health claim approved and I think that the evidence, while it is growing all the time, is not quite there yet."*

The European Food Safety Authority (EFSA) last year approved a health claim for dark chocolate and cocoa beverages that read: *"Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow."* But no health claim or structure/function claim exists in the US.

#### More clinical trials needed

Shumow said: *"We've explored whether or not the criteria for the Food and Drug Administration (FDA) would be met by the research that is available and it is our currently thinking that we're close, but we're not quite there yet. There would need to be more clinical trials."*

The EU health claim, submitted by Barry Callebaut, was backed by five published and one unpublished randomized controlled trials.

*"The threshold of evidence to say something like the EFSA claim would fall into a slightly different category [in the US],"* said Shumow. The FDA makes a distinction between health claims and structure/function claims.

*"A health claim has to do with disease risk, so something like 'cocoa flavanols prevent the risk of cardiovascular disease',"* said the NCA technical director. Structure/function claims by comparison describe the role of a nutrient or functional component in maintaining normal functioning or health.

*"The FDA has much lower standards for a structure/function claim, so if a company felt they had sufficient data to back up structure/function claims on cocoa flavanols and circulations they wouldn't necessarily need pre-approval from FDA to do that. But given the litigation risk and not having such clarity makes it a gray area for companies,"* said Shumow.

#### Nutrient content claim

Barry Callebaut, which holds rights to the EFSA health claim for five years, produces flavanol-rich chocolate through its Acticoa brand. The firm has sold Acticoa in the US since 2005.

*"In the US there were some companies that made a claim that the product contained a certain amount of cocoa flavanols. FDA does allow a nutrient content claim - it's not linking it to a health claim, it leaves it for the consumer to decide,"* said Shumow.

But is consumer knowledge of cocoa flavanols strong enough to be attracted by a nutrient content claim such as 'contains 200 mg of cocoa flavanols'?

*"There have certainly been an increasing number of news stories about cocoa and dark chocolate, but I'm not sure if it's trickled quite down to the consumer level of knowing that the cocoa flavanols are the component of the cocoa that would be attributed to health effects,"* said Shumow.

#### How great is consumer demand?

### Two blocks of enriched dark chocolate a day

EFSA blood flow health claim for dark chocolate is for 200mg of cocoa flavanols daily. This amount of cocoa flavanols equates to 2.5g of Acticoa cocoa powder in a beverage or 10g in Acticoa dark chocolate – which is around two blocks of a 100g tablet.

Barry Callebaut has claimed there is an established market for dark chocolate and strong consumer interest in heart health claims.

But Euromonitor International ingredients analyst Lauren Bandy previously said that a cocoa flavanol claim would be more a novelty than a revolution for the chocolate industry because EFSA's wording was still very technical and chocolate was more an indulgence.

*"I would agree that chocolate products are seen as an indulgence," said Shumow. "Also when it comes to FDA approved health claims; generally speaking these claims are extremely wordy, so they become impractical to be used on labels. However, they do represent that a significant threshold of evidence has been met, so that can be easier to overcome barriers in marketing and communication. It does provide some credibility."*

Recent [research](#) said that dark chocolate may help restore flexibility to arteries and prevent white blood cells from sticking to the walls of blood vessels, but increasing the flavanol content would not necessarily boost these effects and may even put consumers off.

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