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## EFSA: First article 13.1 health claim opinions delayed until September, 2009

By Shane Starling, 15-Jul-2009

**The European Food Safety Authority (EFSA) and European Commission have acknowledged for the first time that the July 31 deadline for publication of the first batch of health claim opinions will not be met.**

EFSA will now publish the first batch of 1024 claim opinions "by September" although a spokesperson was not able to confirm the exact date nor what effect this would have on the ultimate nutrition and health claims deadline of January 31, 2010.

Claims being passed back and forth between EFSA, the European Commission and member states is cited as a major reason for the delay.

Given uncertain timeframes for the risk management stages of the legislation which involves validation of EFSA's opinions by the European Commission and member states, it may be well into 2010 before the long-awaited centralised list of nutrition and health claims comes into play across the 27-member state European Union.

**Staggering**

Sections of industry will also be concerned that while a delay will theoretically allow more time to clarify issues such as nutrient profiling, claim wording and scientific standards and presentation, a staggered approach to claims publication remains in place.

Groups such as the European Federation of Associations of Health Product Manufacturers (EHPM) and the European Responsible Nutrition Alliance (ERNA), have highlighted the business disadvantage that can result from opinions being issued at different times, be they either negative or positive.

"We support the delay but remained concerned about the commercial impact of this regulation as it stands," EHPM regulatory affairs director, Lorène Courrège, told NutraIngredients.com this morning. "It is becoming very obvious there are many issues with this regulation that need resolving and quickly."

Health claims expert, Nigel Baldwin, the senior scientific and regulatory consultant and EU manager at Cantox Health Sciences International, said EFSA should go ahead and publish its opinions as they are finalised.

"It is important to see these opinions sooner rather than later so the debate on how EFSA will assess them can be concluded because clearly they have opinions ready and are unlikely to change them," he said.

But he acknowledged the commercial issues that may arise from staggered publication.

"I would urge caution that they are published, as far as is possible, in groups of similar functional ingredients, so that competitive issues are kept to an absolute minimum because this is a legitimate concern from industry. If they start with some of the vitamins and minerals that would be a way to break into the process slowly and without too much initial controversy."

**Reasons for delay**

The fact more than half of the 4000-or-so article 13.1 nutrition and health claim dossiers were sent back to the Commission for clarification on various points by EFSA is cited as a major reason in the delay.

"The clarification process, which is complex as it involves member states and other interested parties, has not been completed yet," said a statement on the European Union website today.

"Because of this delay it will not be possible for EFSA to evaluate all submitted claims in time to allow the Commission to adopt the Community list of all permitted Article 13 health claims by the set deadline of January 31, 2010."

**Call for discussion**

Courrège said EHPM, which represents 1000s of mostly small to medium-sized players, was disappointed EFSA had made no move to initiate a stakeholder's meeting with EHPM and others after the group recently issued an ulterior model to deal with article 13.1 health claims.

"The process is not working and this delay highlights that," she said. "We want to have a dialogue with EFSA about this but none has so far been forthcoming."

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