



HFMA UPDATE

by Graham Keen,
Executive Director

Regular readers will know that on rare occasions I actually have something more positive to report in these articles. As so it is the case this month.

The work of the HFMA secretariat and its advisers is focused on the 'big issues' like maximum levels and the future for botanicals, but all the time we are constantly working away on less well-known and publicised challenges to the interests of our members.

There are a myriad of relatively minor issues that, in their own way, are still of huge importance to certain member companies. With the festive season approaching fast, this month I will provide an update on four such examples, all with mixed tidings, and only a couple providing anything remotely close to great joy!

In earlier articles this year, I have reported on the HFMA's efforts to secure an Article 14.1 (a) Disease Risk Reduction health claim for folic acid and the reduced incidence of neural tube defects in the unborn child, resulting in a reduced incidence of the terrible disease, spina bifida, in infants. The substantial health claim dossier was compiled and written by the HFMA's own Scientific Adviser, Dr Michele Sadler, and this was approved by the European Food Safety Authority (EFSA) in very remarkably quick time at the end of July this year.

I'm very pleased to report that the approved claim is now progressing quickly through the formal adoption process and the latest news is that the Department of Health (DH) has issued an update on the most recent Commission working group on health claims held on November 18. The agenda included discussion of the folic acid claim and we are advised that, following EFSA's earlier approval of the claim, a draft Commission Regulation has already

been issued, and the discussion at the meeting focused on using the term 'folic acid' in the conditions of use rather than 'folate' and, crucially, making it clear that the claim is for food supplements only. These were points that had been made strongly by the HFMA and argued for on their behalf by the DH representative at the WG meeting.

The draft regulation is now likely to be amended to reflect these changes, and the expectation is that it will be put to a vote at the Standing Committee at the next opportunity, which is expected to be in the second half of January 2014. The end result, with luck, should be a very rare commodity of late – a new health claim that can be used throughout the EU, one of only 220-odd that have survived the health claims process out of nearly 5,000 claims submitted by the EU-wide industry.

One substance used by our industry, and a popular ingredient in many products, is raspberry ketone. The HFMA has received a letter from the Food Standards Agency stating that they believe that raspberry ketone is a novel food and should not be sold as a food/food supplement until it is approved following a novel food application dossier containing safety data. To be considered non-novel, we need evidence of consumption of raspberry ketone as a food or food supplement, to a significant degree, before May 1997 in the EU. It seems almost certain that it will be challenging to prove pre-1997 evidence, but in the meantime the HFMA will be responding to the FSA's consultation on this issue, on behalf of our members and the eventual outcome may well be several months into the future.



Needless to say, similar products, like the one pictured, are marketed freely in the USA, but it seems that even though raspberry as a food flavouring has been readily available in the EU since the year dot, companies here in the UK will again face greater restrictions than their US counterparts.

Last week we learned that, following their industry-wide consultation, the UK medicines agency has, as widely expected, announced that the formal end date for the sell-through of unlicensed herbal medicines under the Traditional Herbal Medicinal Products Directive (THMPD) will be April 30, 2014. This predictable outcome should certainly not have come as a surprise to anyone in the industry, and is the logical end point in a transition process that started no less than 10 years ago.

Last month, I reported on the 'red tape' tangle that we find ourselves caught up in with regard to the Food Additives Regulation, and the 'missing' additives crucial for the production of liquid food supplements for infants and children. The latest on this is that the Commission is still reviewing the absence of approved additives and, following many suggestions and objections to the Food Standards Agency by the HFMA and others on this legal void for our products, the FSA has now written to local enforcement officers in England and Wales advising them not to take action against companies that continue to market these products, which contain additives which were allowed before June 2013, until the Commission has rectified the situation. We are told that this "administrative oversight" by the

European Commission has been recognised, and that an expert Commission Working Group is being arranged to further discuss this. Clearly, there are signs of a positive outcome to this issue, but we are continuing to watch this closely.

Finally, I would like to take this opportunity to offer grateful thanks to the HFMA's erstwhile Technical Adviser, Michael Evans, who has decided to hang up his boots and take a well-earned retirement at the end of December this year. As everyone who has worked with Michael will know, he has done a marvellous job in this role for the HFMA for the last 12 years, and he will be a very tough act to follow. It goes without saying that everyone associated with the HFMA wishes Michael a long and happy retirement, during which he will presumably be closely following the endeavours of his beloved Welsh rugby team.

Moving forward, we are very pleased to be able to announce that the HFMA's new Technical Adviser from January 1, 2014 will be Nigel Baldwin of Intertek Cantox. Many of our members will know Nigel from his attendance at HFMA working group meetings over the years, and his deep knowledge of the industry and the technical issues relating to it. He is also noted for his presentations at many European industry events and was a guest speaker at our own HFMA seminar back in 2010. I am really looking forward to working with Nigel, and I sincerely hope he can successfully follow in Michael's large footsteps. **hfb**

To benefit from the gold-standard advice we provide, join the HFMA at the earliest opportunity. To learn more about our activities, please contact me at graham@hfma.co.uk.

HFMA membership is vital to ensure that your company keeps abreast of the fast-changing regulatory environment. The HFMA is the UK's best source of information and most effective defender of our industry's interests. To help the HFMA defend your business at this most critical time contact hfma@hfma.co.uk or call 020 8481 7100.

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The Voice of the Natural Health Industry