alliance for natural health
good science and good law

ANH INNOVATORS CLUB BULLETIN

Feb/March 2007

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Key Regulatory Developments: Feb/March

ANH puts spotlight on EU procedures for food supplements following European Court judgment

The Alliance for Natural Health (ANH) on 16 March 2007 informed the European Commission that it will scrutinise its procedures and those of the European Food Safety Authority on food supplements, in accordance with a European Court of Justice (ECJ) judgment.

After the ECJ passed its ruling on the ANH's case in July 2005, many consumers, practitioners and companies felt confident that a fair and balanced approach would be used by the European Commission to ensure vitamin and mineral ingredients could be added to the very restrictive 'positive list' of the Food Supplements Directive (Directive 2002/46/EC). This list conspicuously omitted key food sources of vitamins and minerals which are known to be of greater benefit to the body than the synthetic vitamin and inorganic mineral forms which make up the majority of the list. Unfortunately any confidence seems to have been misplaced.

Three months before the judgment, the Advocate General allocated to the case considered the lack of transparency in the procedure for applications to the positive list a fatal flaw and recommended that the Directive be invalidated. However, rather than invalidating it, the ECJ went to considerable lengths in its judgment to 'fix' the lack of transparency in the application procedure. This 'fix', which required full disclosure of procedures, the potential for legal redress, as well as clarification both of the burden of proof and the criteria required for applications, appears to have been systematically ignored by the European Commission and the body responsible for evaluation of dossiers, the European Food Safety Authority.

Rather than continue to engage in fruitless correspondence with the European institutions, the ANH, together with its top flight European lawyers, have set into motion a strategy which it believes will force the European institutions into delivering the approach so carefully set out by the ECJ.

This strategy is based around submitting 15 applications (dossiers) to the positive the list, which it is hoped will directly or indirectly create a precedent. The dossiers submitted meet the relatively narrow criteria clarified by the ECJ, but do not include the more elaborate information that the European Commission had stipulated without an adequate legal basis. The ANH has informed the Commission today that it will scrutinise the entire procedure used to evaluate applications to the positive list as set out by the ECJ,

Should the EFSA refuse any of the ANH's applications, the ANH will pursue a legal challenge through the courts according to the process outlined by the ECJ in its judgment on the ANH's case. Such a challenge could be central to the establishment of a proper precedent for applications to the Directive's positive list, applying not only to vitamins and minerals, but also to other nutrients such as botanicals, amino acids and essential fatty acids.

(See full press release attached and link to article on Nutraingredients: http://www.nutraingredients.com/news/ng.asp?id=75066-alliance-for-natural-health-vitamins-minerals)

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The full list of ANH dossier applications to the Positive List

Annex I:
Vanadium
Sulphur
Boron
Silicon
Strontium
Lithium
Germanium
Silver
Tin

Annex II:
Food-derived folates (including 5-MTHF [not calcium salt]) (generic)
Wheat germ oil, as a source of full spectrum vitamin E (generic)
Mixed carotenoids (generic)
Caromin® (proprietary mixed carotenoids from palm)
Tocomin® (proprietary mixed tocotrienols from palm)
Strontium carbonate

European Union

RIA for setting Maximum Permitted Levels

The European Commission is pushing a very hard line on this and it is not at all beyond the bounds of possibility that final maximum permitted (daily) levels for supplements might be at the levels developed by the Federal Institute for Risk Assessment in Germany (BfR), which includes zero tolerance for several nutrients (see third column in table below):

BfR Maximum Permitted Levels for supplements: Extracted from p. 23 of BfR report, *Use of Vitamins in Foods*, 2005 (these levels should be viewed as worst case scenario)

Nutrients		Recommended daily intake for adults [1]	Proposal for maximum level in FS	Comments
Vitamins				
Vitamin A	µg	800	400 (only for adults)	for children aged between 4 and 10: 200 µg
Beta-carotene	mg	2-4 [2]	2	
Vitamin D	µg	5	5	for persons >65 years: 10 µg
Vitamin E (equivalents)	mg	11-15 [2]	15	
Vitamin K	µg	80 [2]	80	
Vitamin B_1	mg	1.3	4	
Vitamin B_2	mg	1.5	4.5	
Niacin	mg	17	17	no use of nicotinic acid
Vitamin B_6	mg	1.6	5.4	
Folate equivalents	µg	400	400 (as folic acid)	
Pantothenic acid	mg	6 [2]	18	
Biotin	µg	60 [2]	180	
Vitamin B_{12}	µg	3	3-9	
Vitamin C	mg	100	225	
Minerals				
Sodium	mg	550 [3]	0	
Chloride	mg	830 [3]	0	
Potassium	mg	2000 [3]	500	
Calcium	mg	1000-1200	500	
Phosphorus	mg	15 to <19 y: 1250 from 19 y: 700	250 (as phosphate)	
Magnesium	mg	15 to <19 y: 400/350 19 to <25 y: 400/310 25 to <65 y: 350/300 65 years and older: 350/300 (m/f)	250	where appropriate, break down into 2 single doses
Iron	mg	15 to <19 y: 12/15 19 to <51 y: 10/15 51 y and older: 10/10 (m/f)	0	
Iodine	µg	180-200	100	
Fluoride [4]	µg	15 to <19 y: 3.2/2.9 19 to 65 y and older: 3.8/3.1 (m/f)	0	
Zinc	mg	7 (f) 10 (m)	2.25	no supplements for children or adolescents under the age of 18
Selenium	µg	30-70	25-30	
Copper	µg	from 15 y: 1000-1500 [2]	0	
Manganese	mg	2-5 [2]	0	
Chromium	µg	30-100 [2]	60	
Molybdenum	µg	50-100 [2]	80	maximum level not suitable for children under the age of 11

We have received notification from the UK Food Standards Agency that the EU Commission may bring forward proposals on the establishment of maximum daily dose levels of vitamins and minerals in food supplements by end 2007. As such they are seeking to draw up a Regulatory

Impact Assessment (RIA) of the likely impact of such provisions, and submissions from stakeholders are requested by **25th May 2007.** The ANH will be seeking input from its Innovator Club members to ensure that 'our' collective voice is represented and individual products are covered.

If all the scientific and lobbying pressure from the ANH and other organisations fails, it is still possible, owing to new comitology procedures (see http://www.europarl.europa.eu/oeil/file.jsp?id=5362062) introduced in July 2006, to block the passage of the implementing measure that the Commission will use to turn MPLs into law EU-wide. There will be strong opposition from certain influential MEPs on this, including ex-UK Minister for Health, John Bowis, who is a 'friend' of the ANH.

It appears now that likely timing for proposed final implementation might be 2009.

Traditional Herbal Medicinal Products Directive (THMPD)

At the moment the UK is allowing dual use of a variety of herbs both as food supplements and as medicinal herbs under THMPD. However, the Committee for Herbal Medicinal Products is currently preparing its monographs and it is quite possible that some herbs will be allowed as licensed medicinal products only, especially in some Member States, such as Germany. Accordingly, owing to different interpretations of the THMPD in different Member States, it is unlikely that total harmonisation between Member States will be achieved in relation to herbal medicinal products. It may be another year or so until this is known.

It will be more or less impossible to register polyherbal combinations or combinations with nutrients as licensed products, as THMPD primarily applies to only single herbs. There are technical difficulties (notably stability) that make it very difficult or impossible for polyherbal complexes to meet the eligibility criteria and the Directive states that vitamin and mineral components can only be "ancillary" to the herbal content. Licensing, which will be undertaken through Member State competent authorities dealing with licensed medicinal products, will also be prohibitively expensive for all but the largest companies. Costs may exceed €50,000 for a single herb).

URGENT: calls for action
Company response required!

1. Companies wishing to apply for generic Article 13 Health Claims should do so immediately. Closing date for submission of Article 13 claims in the UK is September 2009. Please see letter from the UK Food Standards Agency attached. **Please make contact with us to discuss this further and ANH Consultancy Ltd is able to provide support for such applications on a consultancy basis. Alternatively make use of the 2 h free consultancy we offer every month for ANHIC Gold and Silver members (cannot be accumulated or carried forward to next month).**

2. Companies wishing to apply for the Positive List regarding vitamin and mineral supplements should be considering this seriously now – the ANH strongly recommends this course of action, rather than relying on existing derogations. Derogations can be withdrawn at any stage if an unfavourable review is given by EFSA and the derogation phase expires on 31 December 2009. **Please make contact with us to discuss this further and ANH Consultancy Ltd is able to provide support for such applications on a consultancy basis.**

3. **US Innovators:** Charitable tax deductible donations (for US individuals and companies) can be made to the ANH via our US affiliate the American Association for Health Freedom/Health Freedom Foundation. Donations should be sent to The Health Freedom Foundation clearly marked that the gift is in support of European or global work.

The Health Freedom Foundation
4620 Lee Highway, Suite 210
Arlington, VA 22207
Phone: 1800 230 2762 or 703 294 6244 or Fax: 703 624 6380

Note to US companies: We would be extremely grateful if you could publicise this method of making charitable tax deductible donations to the ANH from within the US to your customers in any marketing literature you are about to send out.

Please email our Development Manager, Meleni Aldridge, at mel@anhcampaign.org or telephone +44 (0)1306 646 550.

ANH Publications

Some recent ANH publications are given below:

Publication	Content	Format	Date	Distribution
Caduceus Magazine	Contaminants in drinking water	Article	Autumn 2006	UK mainly (consumers & practitioners)
Caduceus Magazine	The dangers of exposure to chlorine in water	Article	Winter 2006	UK mainly (consumers & practitioners)
Food Magazine	2006 EU regulatory review	Article	Winter 2006	EU wide trade publication
Pharmacy Business	Natural products for pain	Article	January 2007	All UK pharmacies
FDA Week	ANH/AAHF FDA submission	Article	January 2007	US FDA trade publication
Positive Health Magazine	Natural products in event of H5N1 pandemic	Article	February 2007	UK, EU, USA (consumers & practitioners)
Natural Products News	UK MHRA criminalises vitamin seller	News item	February 2007	UK trade publication
Nutraingredients Europe	ANH legal strategy re FSD 2007	Article	March 2007	Worldwide online circulation
Positive Health Magazine	Sustainable Healthcare	Regular column	March 2007	UK, EU, USA (consumers & practitioners)
Integrated Health Magazine	Maximum Permitted Levels	Regular column	March 2007	UK (mainly practitioners)

USA

ANH/AAHF submission to FDA on Functional Foods

The following article written by Jennifer Smith, appeared in *FDA Week* on 12th January 2007, following a telephone interview with Dr Robert Verkerk regarding the ANH/AAHF submission on functional foods.

NATURAL HEALTH GROUP FEARS EUROPEAN FUNCTIONAL FOOD REGULATIONS

Jennifer Smith
FDA Week
Date: January 12, 2007

A natural medicine advocacy group is urging FDA to not adopt functional food regulations similar to standards Europeans are pushing because they fear the European approach will drive smaller companies out of business and reduce consumer choice. They say the Europeans are pushing drug-like standards for dietary supplements and functional foods that would benefit large companies that could afford clinical trials.

The American Association for Health Freedom (AAHF) and its European affiliate, the Alliance for Natural Health (ANH), expressed concerns in comments filed to FDA Jan. 4. They warn against "data requirements so extreme that only the very largest food companies will be able to meet them."

AAHF Scientific Director and ANH Executive Director Robert Verkerk says an international template on functional foods and vitamin and mineral supplements is being developed through the Codex Alimentarius Commission, which is in turn influenced by food and dietary supplement laws developed by European member states. He says such stipulations will likely influence the United States, which is a Codex member.

Codex is an international food standard-setting organization established by the World Health Organization and the Food and Agriculture Organization of the United Nations.

"If the United States does not take a lead now, it might well find itself outvoted in future Codex discussions, leading to the potential collapse of America's current functional foods and dietary supplements markets," the petition warns.

Europe is asking for functional food makers, for example, to provide randomized controlled trials demonstrating their product's health effects. They also are banning supplements that contain functional ingredients, such as vitamin C, above recommended daily values.

"The cost of setting up randomized controlled trials rather than observational evidence or epidemiological evidence or case reports benefits large companies," Verkerk says. Such requirements are typical for a drug application and should not be applied to foods.

The organization agrees with human studies, but also supports animal, cell and molecular studies as supporting evidence.

AAHF/ANH ask for functional foods to be named as sub-categories of conventional foods and all aspects of food law apply. They also ask for FDA to expand the definitions of nutrition and health claims to functional foods as currently regulated under the Dietary Supplement Health and Education Act.

"The U.S. pretty much has a liberal regime that accepts structure- function claims and limited health claims for dietary supplement. Europe in particular has not allowed any significant claims to be made for any product that is not a drug," Verkerk says.

FDA held a hearing in December on a proposed regulatory framework for functional foods.

Like other segments of the dietary supplement industry, AAHS/ANF opposes a stringent regulatory framework for functional foods. But if FDA adopt strict measures, the group offers numerous recommendations in their petition for how FDA should regulate such foods.

For example, their petition proposes two distinct levels of health claims, one involving structure-function claims that use the same framework presently used under DSHEA, the second being more specific, authorized by a relevant scientific body and involving a higher degree of scientific substantiation which would be categorized according to the three-tier World Health Organization system (conclusive, probable or possible claims).

The former, the structure-function claim category, would require 30 days premarket notification, while the second, authorized health claim category would require 120 days premarket notification.

Authorizations would be agreed on by consensus of a task force comprised of government, industry, consumer and academic representatives, affiliated with a recognized and appropriate scientific body, such as the National Academies of Science or National Institutes of Health.

AAHF/ANH propose in their petition criteria for establishing both safety and efficacy of ingredients to be used in functional foods. Categories suggested are:

* GRAS (either use of the existing definition or a new category to cater for novel [post-1958] substances). The criteria required for the latter category, possibly called Novel-GRAS, should be “less onerous” than those currently required for GRAS category.

* GRAE (as proposed by the Institute of Food Technology in their presentation to FDA at the functional foods hearing last December). IFT has proposed a panel of independent experts determine the efficacy of the component under consideration.

* GRASIU (a specific category of potentially more dose-sensitive ingredients regarded as safe for their intended use, as proposed by AAHF/ANH). Such a category could fit ingredients regarded by qualified experts as generally unsafe in high concentrations, or in combination with other ingredients in food or medicines, but at the same time, are considered by the same experts to be both safe and beneficial in their defined intended use.

* Negative list (ingredients that should not be used in functional foods). These would be developed as a result of rejected applications.

AAHF/ANH agrees with criticism levied by IFT that the term “nutritive value” places a restrictive framework on functional foods, and the groups support IFT’s proposal that claimed benefit be based either on nutritive value or on the provision of a physical or physiological effect that has been scientifically documented or for which an appropriate body of evidence exists for plausibility.

AER bill update

Our international affiliate, American Association for Health Freedom has hired a new government affairs team in order to better represent health freedom interests.

The main lobbyist is well-known in the health freedom community – Dr. William Duncan. Currently he serves as Senior Vice President of Capitol Hill Consulting Group, where he represents clients in the education, health care and biomedical research arenas. His clients

benefit from his extensive background in the congressional appropriations process and health care regulation.

Dr. Duncan served for the last 10 years as the Appropriations Committee Associate staff member on the Labor, HHS, Education subcommittee for Congressman Ernest Istook of Oklahoma. During his congressional service he also handled welfare, Veterans Affairs, Commerce Justice State appropriations, taxation, plus the economy and budget. His projects included: Child Internet Protection Act; Balanced Budget Amendment, Grants Reform to curb lobbying by non-profits with tax dollars; National Labor Relations Board reforms; creation and implementation of the community-based abstinence education program; National Institutes of Health initiatives in setting research priorities & restructuring, Metals-in-Medicine research, hyperbaric oxygen research; CDC initiatives in environmental medicine, amputee services, chronic disease including diabetes, and public health; as well as AHRQ and evidence-based medicine initiatives to expand translational research. He dealt with CMS/Medicare/Medicaid problems including reducing the regulatory burden on health care & prescription drug issues, reducing amputations with hyperbaric oxygen, FDA issues, biomedical research infrastructure; & entitlement reform. He served on several leadership task forces including: Railroad Retirement Board restructuring; creation of the National Center for Complementary & Alternative Medicine at NIH, Commissioned Corps reform, and Medical Innovation & Treatment Access.

The political strategist is Jim Davidson who for more than 20 years, has helped companies and business associations define and achieve their goals in the legislative and regulatory arenas of the federal government. Prior to founding Davidson & Company, his service on Capitol Hill included Chief Counsel and Staff Director for the Senate Judiciary Subcommittee on Administrative Practice and Procedure and Chief Counsel of the Governmental Affairs Subcommittee on Intergovernmental Relations.

Davidson & Company has helped its clients address a broad range of public policy areas including advertising regulation and commercial speech, appropriations, taxations, health care, telecommunications and the Internet.

The new government affairs team of AAHF has already started on the agenda for 2007. One of the first items on the list is to draft a national bill (working title) The Science Free Speech Act. Among some of the items this would cover, would be to allow dietary supplement makers to cite independent scientific research on supplements.

In essence, the bill states no government agency shall censor or otherwise forbid the dissemination or accurate summarization of legitimate scientific research or scientific information that does not have a national security classification.

Look for more information on this bill to follow.

Nutri-Con and NOSG

The US Organic Consumers Association (OCA) have, on 12th March 2007 at Expo West, launched their "Nutri-Con" campaign to expose what they refer to, *as 'rampant labeling fraud in the $20 billion vitamin and supplements industry'.*

Through a major public awareness campaign, as well as litigation where necessary the OCA's Nutri-Con campaign intends to expose the hazards and limited effectiveness of synthetic vitamins and supplements, thereby striving to create mass consumer and marketplace demand '*for truly organic, "naturally occurring" vitamins, botanicals, and supplements*'.

The full press release can be seen at the following link:
http://www.organicconsumers.org/articles/article_4409.cfm

Running in close collaboration is the Naturally Occurring Standard Group (NOSG), which has been established for the purpose of instituting the Naturally Occurring Standard (NOS). The NOS is initially for the purpose of identifying, certifying, labeling, and verifying the naturally occurring vitamins and nutrients in all food products including bulk food materials, nutritional supplements and fortified foods and for the purpose of expressing a clear distinction between

naturally occurring vitamins and nutrient containing products and those that contain synthetic vitamins and nutrients.

Read more from the NOSG website at http://www.nosg.org.

Some of the key issues raised by the OCA and NOSG debate are dealt with usefully in an article by Michelle Knott published in the UK magazine, *Food Manufacture*, (1 Feb 2007). The full article can be seen in Annex I of this bulletin for ease of reference or can be downloaded at the following link:
(*http://www.foodmanufacture.co.uk/news/fullstory.php/aid/4306/Natural_good__taste.html*)

ANH Comment

We appreciate that many companies will not be supportive of the present Nutri-Con campaign given that it is critical of synthetic forms of nutrients, which are widely used in the industry, and many of which are both effective and do not contribute to harmful effects.

We are dialoguing with the OCA at present and helping them to recognise that it may be more productive for them to focus on the 'truth in labelling' aspect of their campaign and the provision of logos, symbols and accreditation for natural forms of nutrients, as well as 100% natural products, rather than attacking the presence of synthetic nutrients. These ideas have been well received and it appears likely that the campaign will in the near future have a shift of focus.

For further information about the ANH,
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ANNEX I

Natural good taste

Shortages of natural ingredients are not the only problems inhibiting their more widespread use, there are cost and technical issues too, says Michelle Knott

By Michelle Knott
Published: 01 February, 2007

It would be easy to fill an entire magazine with arguments about the wisdom or idiocy of the trend towards natural flavours. People who have spent their working lives in the flavours industry get hopping mad about how out of touch consumers are with scientific evidence about the safety and effectiveness of synthetic ingredients.

But there is one fact that is impossible to argue with - the juggernaut of public opinion will not change course any time soon. A growing army of British consumers is demanding food with only 'natural' flavours, regardless of whether there is any science to support the notion that they are 'healthier' or 'better'.

The natural ingredients bandwagon is the market reality and food manufacturers are jumping on board. "We're seeing a dramatic growth in the demand for natural ingredients, even in the last 12 months," says Steven Pearce, md of Omega Ingredients and president of the British Society of Flavourists (BSF). "People used to say they were fine with nature identicals but now they are all asking for natural flavours."

Keeping it real

You might expect him to be rubbing his hands with glee at the prospect. After all, Omega counts a wide selection of natural and organic products from suppliers around the world among its range. Surely the trend towards naturals is good for business? But Pearce takes a wider view: "It's what everyone's dreaded in a way. We simply don't grow, anywhere in the world, enough of the necessary crops to give everyone natural flavours."

"It's a bit like organic food," agrees consultant, Dr David Baines. "If everybody bought organic we'd have problems with food supply. I've seen a calculation done that said that if we had to replace raspberry flavour with naturally extracted raspberry then the whole of England would be covered with raspberries."

The supply problem is exacerbated by the fact that British consumers tend to be pretty conservative in their choice of favourite flavours. "In 2004-5 there were around 5,000 new food products launched in the UK. Of all those products, the predominant favours were still strawberry, raspberry, chocolate, orange and vanilla. It doesn't matter how many exotic ice creams there are out there, people still like strawberry, chocolate and vanilla," says Pearce. "How on earth are we going to supply enough?"

Blame the weather

The other big supply problem is that many of our favourite flavours come predominantly from one or two parts of the world, leaving the supply extremely vulnerable if things go wrong. Treatt supplies essential oils and other raw materials to the flavours industry, and can cite a variety of cases where 'localised' problems have had a significant knock-on effect on world prices.

For example, Argentina is the world's biggest lemon oil producer. In 2000, over 60% of the vital Tucuman province was underwater, while in 2003, the same area suffered a drought that reduced the lemon crop by 25%.

Hurricanes in 2001 ripped the grapefruit from the trees in Cuba. And when the same thing happened in the US in 2004, it pushed up the price of grapefruit oil to around eight times its previous level.

But perhaps the most dramatic example of all is vanilla. "Vanilla has been through a real rollercoaster," says Giles Bovill, marketing manager for Treatt. "In 2003 it was at ridiculous prices and now it's back at an all time low."

The price spike was caused by a combination of hurricane damage on Madagascar and a difficult political situation on the island. "The price of vanilla beans shot up by 10 times," says consultant and founding member of the BSF, Jack Knights.

"But it wasn't just the weather. A major reason was the political situation. The trouble is that a lot of these raw materials come from countries that aren't very stable."

And even when the political situation in a source country is relatively sedate, crops can still be vulnerable to the whims of social politics. According to Pearce, blackcurrants are a good example of this: "There are two reasons why blackcurrants are in short supply at the moment. First, it's because there was a very hot summer in Poland and that affected the crop. Second, there aren't enough people to pick them because many workers have moved to western Europe looking for better wages. And we're seeing the same situation with raspberries."

Technical hurdles

But uncertain supplies are merely the first challenge of going natural. Relying on natural extracts also presents significant business and technical hurdles. "It's possible to have natural flavours but they're expensive and they don't work very well except at high levels," says Knights.

"In nature, the actual flavour compounds are often present at parts per million, parts per billion or even lower concentrations," says Baines.

When you take into account the greater quantities needed to get a good result, Knights estimates that many food manufacturers face bills for natural flavours that are 10 times higher than when they use synthetic ingredients.

But it's a premium that manufacturers must pay in the drive for 'clean' labels and consumer acceptance. "It really comes down to how you want to label the finished food," says Knights.

Precisely what manufacturers will and will not be able to claim on their labels is currently causing considerable concern, with the new Food Improvements Agent Directive (Directive 88/388/EEC) poised to spawn fresh European regulations in as little as two years' time (Food Manufacture, October 2006).

Basically, however, the rule is that a natural flavour can be produced from a natural source material only by physical, enzymatic or microbiological processes. If you want to call it natural strawberry flavour, 90% of it has to be derived from strawberry and the other 10% must be from other natural sources.

"So your flavour may be 90% concentrated natural strawberry juice, but it's the other 10% that is usually responsible for most of the flavour and that can be made up of any natural material, including naturally produced chemicals," says Knights.

"Consumers think that natural strawberry flavour is just made from strawberries, but it's not. An increasing number of normally used synthetic flavour chemicals are being produced by these [physical, enzymatic and microbiological] processes. The flavours industry is doing a lot of work to find methods of making natural versions of the flavour chemicals it has traditionally used," he says.

Variability is the other technical bugbear of using natural flavours. "The 10% ingredients can go some way to mitigate any variability, although even these compounds are from natural sources and are still quite variable as a result," says Knights.

Stability and shelf-life are also considerations, but not necessarily because of the nature of the flavours themselves. "At the same time as they're calling for natural flavours, retailers and consumers are asking for preservatives and antioxidants to be taken out, so manufacturers have to resort to alternative approaches, such as modified atmosphere packaging," says Pearce.

Back to the soil

Many of these issues will be all too familiar to those manufacturers in the organic sector. For these companies, flavour houses are increasingly offering specialist products from organic sources. In fact, the European rules on organics (EEC 2092/91) say that the flavours used in organic products must be "natural and extracted by physical means", and do not specify that the source of the flavour has to be grown organically.

The Soil Association - Britain's largest organic certification body - bases its guidance on these rules, but takes things a step further. "If the flavour isn't named, you can use a natural flavour from a non-organic source, but we have an extra requirement for named substances," says Keith Ball, head of processor technical services. "If you want to market 'organic mint tea', the mint would have to be grown organically."

The Soil Association also specifies that the only solvents that can be used in the extraction process are water, ethanol or carbon dioxide. Again, the ethanol doesn't have to be from an organic source for general natural flavours, but it must be organic in the case of a named flavour.

There is also confusion about the "5% rule" for organic food, which says that manufacturers may use up to 5% of non-organic agricultural ingredients in their products and still label them as organic. However, Ball is clear that this does not apply to flavours, which are counted under additives and processing aids, rather than agricultural ingredients.

"The whole situation is very confusing," admits Ball. "And with new regulations and new people coming in with new products all the time, it's only going to get more complicated."

In the end, cost will probably do more than any moral or scientific arguments to encourage consumers to opt for synthetic flavours. "This whole trend is really driven by a few people who can afford to buy organic food from the organic shelf whatever the cost, but the average man in the street simply can't afford to do that," says Pearce. FM

KEY CONTACTS

* British Society of Flavourists 01925 758628
* Omega Ingredients 01473 836400
* The Soil Association 0117 314 5000
* RC Treatt 01284 702500