January 17, 2008

European Food Law Update

EUROPEAN UNION

1. Additives and Flavourings

Re-Evaluation of Food Additives - The European Commission published a report and annex on the progress of the re-evaluation of food additives on 18 July 2007. The report provides a summary of the recent additive re-evaluations undertaken by the Scientific Committee on Food and the European Food Safety Authority (EFSA).

Red 2G - Following an evaluation of the food colouring Red 2G (E128) by the EFSA, legislation is now in force which bans its use in food in the EU. Regulation (EC) No 884/2007 of 26 July 2007 suspends the use of Red 2G in food and the placing on the market and import of foods containing Red 2G. Foods legally placed on the market or dispatched from a third country before the Regulation came into force on 27 July 2007 can still be sold up until their expiry date.

Smoke Flavouring - The EFSA is currently evaluating the safety of a number of smoke flavourings. On 21 June 2007, the EFSA published a risk assessment on the smoke flavouring primary product, FF-B. The Panel concluded that the flavouring can be regarded as weakly genotoxic *in vivo* and was not able to establish its safety in use when added to food.

Hyperactivity in Children - The EFSA has reviewed research commissioned by the UK Food Standards Agency (FSA) that suggests a mixture of certain food colours and the preservative sodium benzoate could increase hyperactivity in children. A press release issued by the EFSA on 28 September 2007 announced a further detailed assessment of the study is required. The EFSA will review all currently permitted food colours and will prioritise the six colours used in the study. The EFSA expects to complete its assessment by the end of January 2008.

Authorisation of Food Additives - The European Commission accepted European Parliament amendments on 24 October 2007 for four proposals that will introduce harmonised EC legislation on food enzymes for the first time and amend current rules for flavourings and additives.

- Amended Proposal (COM(2007) 672) for a Regulation establishing a common authorisation procedure for food additives, food enzymes and food flavourings (COM(2006) 423);
- Amended Proposal (COM(2007) 673) for a Regulation on food enzymes and amending Directive 83/417/EEC, Regulation (EC) No 1493/1999, Directive 2000/13/EC, and Directive 2001/112/EC (COM(2006) 425);
- Amended Proposal (COM(2007) 670) for a Regulation on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Regulation (EEC) No 1576/89, Regulation (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC (COM(2006) 427); and
- Amended Proposal (COM(2007) 671) for a Regulation on food additives (COM(2006) 428).

2. GMO and Cloning

Animal Cloning - The EFSA launched a public consultation on its draft opinion on products from cloned animals on 11 January 2008. The draft opinion concludes that meat and dairy products from cloned animals is probably safe for human consumption. The work follows a request from the European Commission to the

EFSA for advice on this issue in February 2007. The EFSA's opinion will help inform consideration of any future EU measures in relation to animal clones and products obtained from these animals.

GMO Bt10 - Commission Decision 2007/157/EC of 7 March 2007 repealed Decision 2005/317/EC on emergency measures regarding the non-authorised genetically modified organism (GMO) Bt10 in maize products.

Maize - The EFSA issued an opinion, adopted on 13 September 2007, on the placing on the market of herbicide-tolerant genetically modified (GM) maize GA21 (Unique Identifier MON-ØØØ21-9). The GMO Panel considered that the information available for maize GA21 addressed the scientific comments raised by the Member States and that maize GA21 is as safe as its non-GM counterparts with respect to potential effects on human and animal health or the environment.

3. Categories of Food

Organic Foods - Council Regulation (EC) 834/2007 on organic production and labelling of organic products was published on 20 July 2007. When this Regulation applies from 1 January 2009, it will repeal the existing Regulation (EEC) 2092/91. The new rules aim to improve traceability and consumer information for organic products and they lay down more explicitly the objectives, principles and production rules for organic farming. Under the new Regulation, companies will only be able to label foods and other products as organic if at least 95% of the ingredients by weight are organic. It also clarifies the genetically modified organisms (GMO) rules for organic products.

Food Supplements - The EFSA recently launched a public consultation on the draft approach it proposes for assessing the safety of botanicals used as food supplements. The closing date for comments is 15 February 2008.

Olive Oil - Commission Regulation (EC) No. 702/2007 amending Commission Regulation (EEC) No. 2568/91 on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis applied from 1 January 2008. Products that have been legally manufactured and labelled in the Community or were legally imported into the Community and released for free circulation before 1 January 2008 may be sold until all stocks are used up.

Oilseed Rape - Commission Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC of 25 April 2007 set out measures to be complied with to ensure the effective withdrawal from the market of hybrid oilseed rape and its derived products Ms1xRf1, Ms1xRf2 and Topas 19/2, respectively.

Maize - Commission Decisions 2007/304/EC and 2007/308/EC of 25 April 2007 set out measures to be complied with to ensure the effective withdrawal from the market of Bt176 (SYN-EV176-9) maize and its derived products and products derived from GA21xMON810 maize, respectively.

Energy Drinks - The European Commission requested a scientific opinion from the EFSA on 28 August 2007 on the safety of taurine and D-glucoronolactone as constituents of so-called "energy" drinks. The EFSA will review data submitted in the safety-in-use of these products.

Garlic Supplements - The European Court of Justice (ECJ) published its judgment on 15 November 2007 in the case of *Commission of the European Communities v Federal Republic of Germany* (Case C-319/05). In this case, the ECJ confirmed the status of garlic supplements as foodstuffs following an application from the Commission. The ECJ said that Germany was wrong to refuse an application to import a garlic-containing capsule on grounds that the product was a medicinal product. In doing so, it had infringed the rules on the free movement of goods within the EU.

4. Novel Foods

Revision of Novel Foods Rules - The European Commission published a proposal (see press release) to revise the EC Novel Foods Regulation 258/97 on 14 January 2008. According to the draft Regulation, novel foods would be subject to a simpler and more efficient authorisation procedure, which should enable safe, innovative foods to reach the EU market faster. Additionally, the European Commission is expected to publish the "Novel Foods Catalogue" shortly. The Novel Foods Catalogue is a non-exhaustive list of products

of plant or animal origin as well as of other substances which have been considered in relation to their status within the meaning of the Novel Foods Regulation. It is intended to provide a first orientation as to whether a product would require authorisation under the Novel Foods Regulation or not, where it is intended to be placed on the EU market as a food or a food ingredient.

Oil and Rice Drinks Enriched with Phytosterols/Phytostanols - Commission Decision 2007/343/EC of 15 May 2007 authorised the placing on the market of oil enriched with phytosterols/phytostanols and Commission Decision 2008/36/EC of 10 January 2008 authorised the placing on the market of rice drinks with added phytosterols/phytostanols as novel food ingredients.

5. Foods for Particular Nutritional Uses (PARNUTS)

Guidance - The European Commission issued revised guidance in January 2007 on submissions for safety evaluations of substances added for specific nutritional purposes in the manufacture of foods. The guidance provides detailed information on the procedure that should be followed for the submission of requests for new substances to be considered for inclusion in the permitted lists.

Foods Intended for Use in Energy-Restricted Diets - Commission Directive 2007/29/EC of 30 May 2007 amends Directive 96/8/EC regarding the labelling, advertising and presentation of foods intended for use in energy-restricted diets for weight reduction. The new Directive removes the prohibition on making references to a reduction in the sense of hunger or an increase in the sense of satiety. However, it is still not permitted to make reference to the rate or amount of weight loss which may result from the use of these products.

6. Nutrition and Health Claims

Nutrition and Health Claims Regulation - The European Parliament adopted a Corrigendum to Regulation (EC) No 1924/2006 on 18 January 2007. The Regulation applied from 1 July 2007. The new rules mean that any food product claiming to have a health or nutritional benefit must meet a list of European Commission-approved wording. Certain transitional provisions apply. Nutrition and health claims must be based on and substantiated by generally accepted scientific evidence and food operators making such claims must be able to justify their use.

Generic Health Claims List - Article 13 of the Regulation requires EU Member States to submit a list of draft health claims to the Commission by 31 January 2008, which are claims describing or referring to (i) the role of a nutrient or other substance in growth, development and the functions of the body, (ii) psychological and behavioural functions and (iii) slimming, weight control, a reduction in the sense of hunger, an increase in the sense of satiety and the reduction of the available energy from the diet. This draft list will include claims that are eligible for consideration to be on the final Community list of permitted claims after review by the EFSA. The Commission will adopt the final list by 31 January 2010.

Health Claims Based on New Scientific Data - A recent decision has been made by the European Commission to allow health claims based on new scientific data to be submitted for review next month - two years ahead of its original schedule.

Amendment of Regulation - In January 2008, the European Parliament and the Council adopted an amendment to the Regulation. The amendment provides for transitional provisions for claims referring to children's development and heath.

Guidance - Following public consultation, the EFSA published its final guidance to applicants on the submission of health claims for authorisation on 26 July 2007. The guidance covers what applicants need to include in their applications, in particular the scientific data and evidence required to support the claim(s). The Commission has also issued guidance on the implementation of the Regulation to assist the interested stakeholders to better understand the Regulation and to apply it correctly and in a uniform way.

7. Fortification of Foods

Fortification Regulation - Regulation (EC) No. 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods was published on 30 December 2006 and applied from 1 July 2007. Only

vitamins and/or minerals listed in Annex I, in the form listed in Annex II, may be added to foods. The Regulation also contains provisions for labelling, presentation and advertising of foods to which vitamins and/or minerals have been added. If a substance is identified as having a harmful effect on health, the European Commission may, based on an assessment from the EFSA, list that substance or ingredient in Annex III as a prohibited or restricted substance. Certain transitional provisions apply.

Community Register - The European Commission establishes and maintains a Community Register on the addition of vitamins and minerals and of certain other substances to foods. The Register also lists national provisions on mandatory fortification of certain foods, pursuant to Article 11 of the Regulation.

8. Animal Products and Animal By-Products

Spreadable Fats and Milk Products - Commission Regulation (EC) No. 445/2007 of 23 April 2007 sets out detailed rules for the application of Council Regulation (EC) No. 2991/94 that lays down standards for spreadable fats and Council Regulation (EEC) No. 1898/87 on the protection of designations used in the marketing of milk and milk products.

Milk - Regulation 1153/2007 of 26 September 2007, amending Regulation (EC) 2597/97, lays down additional rules on the common organisation of the market in milk and milk products for drinking milk. The Regulation requires the fat content of drinking milk to be clearly indicated as a percentage on the packaging.

9. Miscellaneous

Furan - In March 2007, the European Commission adopted Recommendation 2007/196/EC on the monitoring of the presence of furan in foodstuffs. The EFSA has called for scientific data on furan in food and beverages. The deadline for submissions is 1 January 2009. The aim of the project is to establish a furan database to gain more data on actual levels of furan found in food to allow a more sound dietary exposure assessment for risk assessment purposes.

Food Contact Materials - The EFSA published a scientific opinion, adopted on 25-26 September 2007, evaluating nine substances intended for use in materials in contact with foodstuffs. Before a substance can be authorised for use in food contact materials, the EFSA must issue an opinion on its safety.

Fusarium Toxins - Commission Regulation (EC) No.1126/2007 of 28 September 2007 setting maximum levels for certain contaminants in foodstuffs regarding Fusarium toxins in maize and maize products applied from 1 July 2007. This legislation amends Regulation (EC) No. 1181/2006 and sets new limits for deoxynivalenol, zearalenone and fumonisins in maize and maize products.

Dietary Fibre - Following a request from the European Commission, the EFSA issued a statement on dietary fibre on 6 July 2007. There is no harmonised EU definition of dietary fibre. The EFSA recommends that the term "fibre" should include all carbohydrate components occurring in foods that are non-digestible in the human small intestine.

BELGIUM

Food Supplements - In November 2007, the Federal Public Service on Health, Food Chain Safety and Environment published guidance on the notification procedure for food supplements. It also further explains the EC and Belgian rules on food supplements.

FRANCE

Health Messages in Advertising - Articles L. 2133-1 and R. 2133-1 to R. 2133-3 of the French Public Health Code, inserted by Decree 2007-263, give companies that manufacture beverages with added sugars, salt or artificial sweeteners or industrial foodstuffs ("*produits alimentaires manufacturés*") the choice between adding health messages to their advertisements and promotions, or paying a tax. The obligation applies to (i) any advertisement; however, for TV and radio advertising, the obligation only applies where the advertisement is broadcast from and received in France, and (ii) any promotion to the public made by printed documents or periodicals published by the manufacturers or distributors of those products. If the company chooses to pay the tax, the tax equals 1.5% of the annual amount allocated to advertising (outside rebates

and VAT) or, for promotions, 1.5% of the production and distribution expenses (outside VAT) paid during the preceding year minus the rebates agreed upon by the providers. Examples of health messages that companies must display are "*Pour votre santé, mangez au moins cinq fruits et légumes par jour*" (For your health, eat at least 5 portions of fruit and vegetables per day), or "*Pour votre santé, pratiquez une activité physique régulière*" (For your health, take a regular physical activity).

Opinion on Regulation 1924/2006 - On 28 June 2007, the National Council for Food ("*Conseil National de l'Alimentation* - CNA") adopted an opinion to clarify the application of Regulation 1924/2006 on nutrition and health claims for foodstuffs. The opinion aims to improve food operators' general knowledge of the new Regulation. The CNA is expected to adopt another opinion that would interpret the Regulation and examine the technical and legal issues it raises.

Salts - On 24 April 2007, the Ministry for Economy, Finance and Industry adopted a Decree on salts intended for human consumption and an Order on nutritional substances that may be used as supplements to salts for human consumption. The Decree sets the ingredient specifications for salts and their sales names. The Order specifies the rules on supplement salts for human consumption with potassium fluoride and iodine compounds.

GMOs - On 19 March 2007, the Ministry of Health adopted a Decree on the deliberate release of GMOs into the environment for any purposes other than placing on the market. An Order on the deliberate release into the environment and on the placing on the market of products composed, wholly or partly, of GMOs and an Order on the collection of information about plantation of GMOs, have also been adopted.

GMO Maize of Monsanto - The French Government announced that it will activate the safeguard clause to suspend the cultivation of the GMO maize MON 810. This decision is based on the conclusion made by the High Authority on GMOs ("*Haute Autorité sur les OGMs*"), in which it expresses doubts on environmental and health impacts of the GMO maize.

GERMANY

Access to Information - A legislative proposal on consumer rights of access to information about foodstuffs ("*Verbraucherinformationsgesetz*") is currently pending. The proposal would allow consumers broader access to information held by authorities. The proposal aims to strengthen consumer rights and, in light of recent food scandals, ensure there is trust throughout the food manufacturing and distribution chain. The legislation was adopted last year, but the President refused to execute the law due to constitutional concerns. The proposal was then submitted through a new legislative process. It is not yet clear when the proposal will be finalised.

Nutrition Information - The German Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) is preparing a guideline for improved nutritional information on food packaging. The aim is to make it easier for consumers to understand nutrition information and to compare specific foods. The BMELV intends to introduce a system that is comparable to the "traffic light" scheme in the UK, but with a slightly different focus. The guideline will promote a "1 plus 4" approach, combining total caloric value ("1") with indication of the fat, sugar, saturated fatty acids and salt content ("4") of one serving of the product, also expressed as a percentage of recommended daily intake. An example of how such labelling is likely to look can be found here.

ITALY

Updated Plant List - In June 2007, the Ministry of Health published an updated list of plants that are not permitted to be used as food supplement ingredients.

Vigilance Programme for Food Supplements - On 15 February 2007, the Conference between the Italian State and the Italian Regions published an ordinance establishing a vigilance programme to monitor the selling and distribution activity of food supplements at sale and distribution points. The inspection activity will aim to check the presence of prohibited plants in food supplements.

SPAIN

Improved Labelling for Coeliacs - The Spanish Ministry of Health and Consumption announced its intention to adopt a decree aimed to improve labelling requirements for all food products containing gluten. The Spanish Food Safety and Nutrition Agency is also evaluating the introduction of a special mark to label gluten-free food.

Nutrition and Health Claims Guidance - On 24 September 2007, the Spanish Food Safety and Nutrition Agency published guidance which clarifies the application of the transitional periods established under EC Regulation 1924/2006 on nutrition and health claims made on food.

Products To Reduce Cholesterol - The Spanish Food Safety and Nutrition Agency published an information paper on food and food ingredients containing plant sterols, plant stanols, plant sterol esters and plant stanol esters marketed with the claim "reduces/helps in reducing cholesterol". The paper is addressed to consumers and summarises basic information about the use of these products and their regulation.

Amendment of Decree on Additives - On 24 August 2007, the Spanish Government adopted Royal Decree 1118/2007 modifying Royal Decree 142/2002 on additives other than authorised colours and sweeteners. The Royal Decree implements Directive 2006/52/EC and modifies the positive list of additives. The Royal Decree, among others, reduces the accepted doses of nitrate and nitrites in meat products, with the exception of some traditional Spanish food products, such as Serrano ham.

THE NETHERLANDS

Acrylamide - The Dutch Food and Consumer Product Safety Authority has recommended that the Dutch government adopts additional measures to decrease the levels of acrylamide in foodstuffs. This recommendation is based on research performed at the request of the Authority by the University of Maastricht. The link between acrylamide and cancer has been verified by animal studies, and confirmed by an epidemiological study on Dutch people over a 20 year period.

Claims Review - The Dutch Food and Consumer Product Safety Authority recently published the results of its evaluation, performed in the second half of 2006, of 79 products for compliance with the rules on food and health claims. The Authority found 44 infringements on 22 products. The claims were assessed under the national legislation. The Authority noted that some of the claims evaluated are no longer allowed under the EC Nutrition and Health Claims Regulation. The Authority announced that it will continue monitoring the use of claims on foodstuffs.

Allergen Review - The Dutch Food and Consumer Product Safety Authority recently announced the results of its evaluation of compliance with the rules on allergen labelling. The authority found that, of all products examined, 5% contained allergens that were not labelled as allergens.

Iodine Fortification - The Netherlands is planning to allow iodine fortification of more foods than is currently allowed under Dutch rules. A draft law has been notified to the European Commission under Directive 98/34/EC. The standstill period, during which the law may not be adopted and the European Commission and other Member States can verify whether the new rules would create barriers to trade, ends on 25 February 2008. The proposed amendment would allow the use of iodized salt in all foodstuffs, but lowers the maximum permitted concentrations of iodine.

UNITED KINGDOM

1. Food Additives and Flavourings

Hyperactivity - A study commissioned by the FSA at Southampton University suggests that certain mixtures of food colours together with the preservative sodium benzoate can increase hyperactivity in children. Two mixes of artificial colours were used in the study. Mix A consisted of Sunset Yellow (E110), Tartrazine (E102), Carmoisine (E122), Ponceau 4R (E124) and Sodium Benzoate (E211). Mix B consisted of Sunset Yellow (E110), Quinoline Yellow (E104), Carmoisine (E122), Allura Red (E129) and Sodium Benzoate (E211). All are approved food additives authorised for use in a variety of products notably confectionary, fine bakery wares, and soft drinks. The FSA referred the results of the study to the EFSA for further review and

held a meeting with representatives from public interest groups and the food industry on 9 October 2007. The issue will be discussed at the next open board meeting in February 2008.

2. GMO

Sampling Guidance - The FSA is seeking comments on supplementary guidance to enforcement authorities for sampling food and feed to determine the presence of genetically modified material. The aim of this guidance is to highlight information on sampling for the presence of GM material, and to provide advice on the most appropriate types of food and feed samples for GM DNA analysis.

GM Rice - Following the incident involving the unauthorised GM rice, LLRICE601, in 2006, and the judicial review in February 2007, the FSA is conducting a review of the incident. The review will consider the views of stakeholders directly involved in the incident and the points raised in the judgment.

3. Food Labelling

Infant Formula - The Department of Health and the FSA announced stricter controls on the labelling and advertising of all types of infant formulae in November 2007. The Infant Formula and Follow-on Formula (England) Regulations 2007 were published to give effect to Commission Directive 2006/141/EC, and amending Directive 1999/21/EC and Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries. Parallel regulations exist in Scotland, Wales and Northern Ireland. The FSA also published a consultation on draft guidance notes in December 2007 and responses are requested by 13 February 2008. However, implementation of this legislation for England and Wales, due to come into force on 11 January 2008, has been suspended. A high court judge has made the order following a legal challenge by the Infant and Dietetic Foods Association (IDFA), which represents baby milk manufacturers. IDFA has applied for a judicial review, challenging the date by which baby milk companies need to comply with the labelling requirements in the new legislation. They believe that the labelling rules should not come into effect until the beginning of 2010. The suspension of the new regulations will be in place until the case has been finalised or another order granted. The court has ordered that the case should be heard before the end of February 2008 but no date has yet been set.

Clear Food Labelling Guidance - The FSA recently published a consultation on its revised draft Clear Food Labelling Guidance. This guidance is intended to help manufacturers, producers and retailers provide food label information for pre-packed foods in a clear way that is helpful to consumers. It sets out legislative requirements and best practice advice.

Criteria for Use of the Terms Fresh, Pure, Natural Etc. - The FSA also published a consultation on its revised draft Criteria for Use of the Terms Fresh, Pure, Natural Etc. in Food Labelling. The guidance sets out legislative requirements relevant to misleading labelling, as well as best practice advice on the use of the terms. Responses are requested by 21 January 2008.

Country of Origin Guidance - The FSA recently published a consultation on its revised draft Country of Origin Labelling Guidance. Key proposals are to revise advice on avoiding misleading labelling with regard to products that are of a particular culinary style and to include best practice advice on labelling where a product is produced in a different country to where it is packed.

Traffic Light Labelling - The FSA published Revised Technical Guidance for front-of-pack traffic light signpost labelling in November 2007. The guidance outlines the nutritional criteria that underpin the red, amber and green (high, medium and low) bands for the 'traffic light' colours recommended by the FSA. As part of its development of traffic light front-of-pack signpost labelling, the FSA commissioned qualitative research to better understand how consumers consider nutritional information in relation to sugars in breakfast cereals. The final report was published in May 2007.

Allergen Labelling - The Food Labelling (Declaration of Allergens) (England) Regulations 2007 came into force on 23 December 2007. These Regulations implement Directive 2006/142/EC (amending Annex IIIa of Directive 2000/13/EC which lists the ingredients that must appear on the labelling of foodstuffs). Two new ingredients are added to that list - lupins and molluscs. The FSA published new guidance notes on allergen and miscellaneous labelling provisions on 21 December 2007.

"Local" and "Seasonal" Labelling - The Local Authorities Coordinators of Regulatory Services (LACORS) Food Labelling Focus Group recently considered use of the claims "local" and "seasonal" to describe food. LACORS reviewed FSA-commissioned consumer research on their understanding of these terms. It seems that consumers have different interpretations of what the terms mean and, as a result, the FSA concluded it will not be possible to provide a definition of these terms for regulatory purposes.

4. Nutrition and Health Claims and Fortification

Nutrition & Health Claims Regulation - The Nutrition and Health Claims (England) Regulations 2007 came into force on 1 October 2007 to provide for the enforcement of EC Regulation 1924/2006 in England. Parallel legislation exists in Scotland, Wales and Northern Ireland. To date, the FSA has published draft guidance to aid compliance with the Regulations and a list of UK health claims to be submitted to the Commission for validation by the EFSA. Final guidance is expected to be published by the FSA in the coming months.

Fortification - The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 came into force on 7 August 2007 to provide for the enforcement of EC Regulation 1925/2006 in England. Parallel legislation exists in Scotland, Wales and Northern Ireland. The FSA has published draft guidance to aid compliance.

5. Novel Foods

Phytosterols - A request was submitted by Lipofoods to the FSA in September 2006 for an opinion on the equivalence of its phytosterols with the phytosterols marketed by Archer Daniels Midland (ADM). The FSA issued a positive opinion in February 2007 and stated that they should be accepted as substantially equivalent.

Noni Juice - The FSA has approved an application to sell noni juice under the simplified procedure. See the FSA approval letter here.

Kiwiberry Concentrate - The FSA is reviewing an application to approve kiwiberry concentrate from the hardy kiwi fruit as a novel food ingredient. The company proposes to market its kiwiberry concentrate as a novel food ingredient in a range of food products.

Algal Extract - The FSA is reviewing an application to approve algal extract from *Haematococcus pluvialis* algal meal, which was granted approval for marketing by a company three years ago as a novel food ingredient under the 'substantial equivalence' process. The company wants to market the algal extract as an ingredient to food supplement manufacturers to be used in capsules and tablets.

Refined Echium Oil - The FSA has initially approved an application to market echium oil, a vegetable oil rich in omega-6 and omega-3 polyunsaturated fatty acids, as a novel food. The applicant wants to use its refined echium oil as a novel food ingredient in a range of foods.

Glucosamine Hydrochloride - The FSA is reviewing an application to market glucosamine hydrochloride as a novel food ingredient in a range of foods. The independent committee concluded that the application requires additional assessment and a decision on authorisation of this ingredient should be taken once EFSA advice is available. See the FSA press release for more information.

6. Foods for Particular Nutritional Uses (PARNUTS)

New Regulations - The Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2007 came into force on 15 October 2007 to amend the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997. The Regulations make several amendments. In particular, they remove the prohibition on using hunger or satiety claims on labelling, advertising or presentation for slimming foods.

7. Food Hygiene and Food Safety

General Food Law Guidance - In July 2007, the FSA published new guidance notes on the General Food Law Regulation (EC) No. 178/2002. The guidance covers issues dealing with food safety, traceability, withdrawal and the recall of unsafe food.

Salmonella Case - A UK court fined Cadbury Ltd £1m in July 2007 for knowingly selling chocolates contaminated with salmonella, which resulted in 42 people suffering from food poisoning. In a prosecution brought by Birmingham City Council, Cadbury Ltd pleaded guilty to three offences contrary to the General Food Regulations 2004 and Food Hygiene Regulations 2006: placing unsafe chocolate on the market; failing to inform the competent authorities; failing to identify hazards from contaminated chocolate and critical controls to ensure food safety.

Safety Report - The FSA published its first annual report on food safety incidents in May 2007. The Agency handled 1,342 investigations of food incidents in 2006, including the high profile national outbreak of salmonella in chocolate and the contamination of US long-grain rice with an unauthorised GMO.

Review of Sudan I - The FSA has published the findings of an independent review of the largest food-related product recall in the UK which resulted from the colour Sudan I in 2005. The colour is not permitted for use in foods in the EU due to its potential carcinogenic properties.

8. Food Advertising

Broadcast Advertising Restrictions - Following a series of consultations and extensive research, in February 2007, the Office of Communications (Ofcom) published a package of measures (see full statement) to restrict the scheduling of television advertising of food and drink high in fat, salt and sugar (HFSS) products to children. The scheduling restrictions came into force in two stages starting on 1 April 2007. Under the new rules, any advertiser wishing to advertise food on television during children's airtime must assess the nutritional composition of their product against the FSA's Nutrient Profiling model. Ofcom also decided that, alongside these scheduling restrictions, revised content rules should apply to all food and drink advertising to children irrespective of when it is scheduled. Ofcom's co-regulatory partners, the Broadcast Committee on Advertising Practice (BCAP) and the Advertising Standards Authority (ASA), are responsible for implementing the new scheduling and content rules and securing compliance respectively. The new rules form part of the BCAP Television Advertising Standards Code. The scheduling restrictions can be viewed here (see Annex 3) and the contents rules can be viewed here.

Non-Broadcast Advertising Restrictions - The Committee of Advertising Practice (CAP) has adopted new restrictions on the non-broadcast advertising of food and soft drink products (except fresh fruit and vegetables) for children under 16 years. They came into force on 1 July 2007 and extend to media such as magazines, paid-for advertising space on the internet, newspapers, billboards and cinema. CAP has produced a Help Note to give advertisers guidance on how the rules are intended to be interpreted and applied.

Advertising Adjudications - (i) Danone Activia Complaint - The Medicines and Healthcare Regulatory Authority (MHRA) complained to the Advertising Standards Authority (ASA) that an advertisement for Danone Activia yoghurts made medicinal claims. The advertisement suggested Activia yoghurts could prevent or reduce a "bloated feeling" and "digestive discomfort". The MHRA considered these were symptoms of indigestion or a digestive disorder and suggested the product could be consumed with a view to modifying digestion. The ASA considered that bloating and digestive discomfort are common consequences of a healthy digestion and it did not believe consumers would think that yoghurts could have the properties of a medicinal product.

(ii) Dairylea Lunchables Complaint - Complaints were made to the ASA about an internet advertisement for Dairylea Lunchables that contained the text "packed with good stuff". The products contained high levels of salt (almost half the recommended daily allowance for children) and saturated fat (more than 5 grams of saturated fat per 100 grams). The ASA noted that the product did contain calcium, vitamin D, wholegrain and protein and that the product did not claim to be low in salt or fat. However the claim "packed with good stuff" suggested the product contained a high proportion of beneficial

ingredients when the product actually contained high levels of salt and fat. The advertisement was held to be misleading.

9. Miscellaneous

Trans-Fatty Acids - The FSA was asked by the Health Secretary in October 2007 to undertake a review of trans fatty acids (TFAs) in light of action that has been taken in Denmark and New York to impose mandatory restrictions on these types of fats. However, a decision was taken at the FSA board meeting on 13 December 2007 to recommend to UK Health Ministers that mandatory restrictions are not necessary in the UK. The reason for this is that voluntary measures to reduce TFAs in food have already resulted in much lower consumer intakes.

Folic Acid - In May 2007, the FSA recommended to UK health ministers that folic acid should be added to bread and controls should be placed on voluntary addition of folic acid to products such as breakfast cereals and spreads. These measures are intended to help prevent neural tube defects, which can result in miscarriage, neonatal death or lifelong disability. The FSA Board gave the Agency the go-ahead to prepare plans to add folic acid to some foods in June 2007. However, in October 2007, the FSA received a letter from the Chief Medical Officer of England requesting that the Scientific Advisory Group on Nutrition (SACN) consider in detail two further studies before any decision on folic acid fortification is made.

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This update has been prepared by Covington & Burling LLP's European food & drug regulatory team. It is intended to provide information on European Community regulatory developments that may be of interest to the food and drink sector and related industries. The information is not exhaustive and Covington & Burling LLP cannot be responsible for any information that is provided on third party websites that are referred to in this update. National developments must also be considered when marketing products in Europe and are only occasionally addressed here.

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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