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Review of Changes in UK Food and Feed Legislation April 2007 – March 2008

Statutory Analysis
Government Chemist
Programme

October 2008



**Setting standards
in analytical science**

Report:

Review of Changes
in UK Food and Feed
Legislation
April 2007 –
March 2008

Statutory Analysis
Government Chemist
Programme

Contact Point: M Walker

Tel: 020 8943 7414
Michael.walker@lgc.co.uk

Prepared by:
Michael Walker

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INTRODUCTION

This is the third and final review undertaken as part of the project RF1 (Milestone RF1/3c) in the Government Chemist 2005-2008 programme. It covers changes in UK food and agricultural legislation that have taken place during the period April 2007 to March 2008 and are important to stakeholders especially those that relate to chemical measurement and the role of the Government Chemist.

The first report¹ (to which readers should refer) provided some background to the legislation to show why, as well as how, it has changed and to provide an insight into the reasons for the existence of statutes in the areas covered.

The second report² grouped legislation into five categories and this is continued in this report. The first three reflect the three primary objectives of food law while regulatory issues and animal feed and fertilisers make up the remaining two. Thus the structure and content of the report are as follows:

- Food Safety, including contaminants and additives;
- Consumer Choice and Prevention of Fraud – including composition and general labelling;
- Health and Nutrition – including nutrition labelling, nutrients and supplements;
- Regulation – dealing with regulatory activities and overarching provisions;
- Feedingstuffs and Fertilisers – dealing with animal feed and fertilisers.

European measures are normally listed firstly along with the implementing domestic legislation followed by purely domestic legislation. English regulations are cited in the text; however for significant measures, where equivalent regulations have been made at the same time for Scotland, Wales

¹ [Farnell, P. Government Chemist - Home - Publications - Foresight Reports](#)

² [Walker, M. Government Chemist - Home - Publications - Foresight Reports](#)

and Northern Ireland, references are given. Potentially temporary and local measures such as prohibition legislation for shellfish harvesting areas have not been recorded. European, domestic and where relevant EFSA consultations and reports are included.

For any specific legislation this document should be read with the actual measure and any view, information or advice given by the Laboratory of the Government Chemist is formulated with care, but is based necessarily upon the information and data available. No responsibility can be taken for the use made of this document and readers must always come to their own view on legislation in force, with expert public analyst or legal assistance if appropriate. In particular, any view, information or advice given should not be taken as an authoritative statement or interpretation of the law, as this is a matter for the courts.

The sources of information used have been The UK Daily List, Office of Public Sector Information ([OPSI](#)), Food Standards Agency updates and the European legislative information database, [Eur-Lex](#). Further information can be obtained from [University of Reading, Dr David Jukes](#) - a comprehensive web based resource - and from the [Association of Public Analysts training guides](#). Extensive use has been made of the explanatory notes that accompany each set of domestic regulations.

ACKNOWLEDGEMENTS

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FOOD SAFETY

Contaminants

Mycotoxins

Following the major consolidation of limits in the Contaminants in Food Regulations 2007³ implementing Commission Regulation (EC) [No. 1881/2006](#), the pace of new legislation in this area slowed, although analytical activity remained high. This was in part prompted by Commission Decision 2006/504/EC to step up import control from certain countries⁴, significant rates of non-compliance and food recalls, the prevalence of which for contaminants exceeds all other categories in the Government Chemist recall data⁵.

Regulation 1881/2006 was amended, for Fusarium toxins in maize and maize products, by [Commission Regulation 1126/2007](#) of 28 September 2007 laying down revised maxima for deoxynivalenol, zearalenone and fumonisins. This was given effect in the UK by the [Contaminants in Food \(England\) \(Amendment\) \(No 2\) Regulations 2007](#) with equivalent devolved measures in [Scotland](#), [Wales](#) and [Northern Ireland](#).

Decision 2006/504/EC was tightened by a [Commission Decision](#) of 19 November 2007 on import control of nuts from Brazil. While Brazil nuts in shell and mixtures of nuts or dried fruit from Brazil remained subject to sampling and analysis of every consignment, the new decision required 50% of consignments of peanuts from Brazil to be sampled for analysis. This was enacted in law in England in early 2008 by Declaration under Regulation 33 of

³ See the second report in this series:

http://www.governmentchemist.org.uk/dm_documents/Food_legislation_2006-2007_EJxK0.pdf

⁴ [Commission Decision](#) 2006/504/EC

⁵ [Government Chemist - Home - Publications - Food Product Recalls](#)

the Official Feed and Food Control Regulations. The same procedure was used for Scotland, Wales and Northern Ireland.⁶

The 2006 FVO mission to assess control systems in the USA for aflatoxin contamination in peanuts and in almonds reported on 14 September 2007. Favourable findings meant that import controls on aflatoxins in peanuts and derived products from the US could be relaxed as approved by [Commission Decision 2008/47/EC](#) published in January 2008. The Decision was applicable from 1 December 2007 and requires the results of sampling and analysis for aflatoxins to be performed by a USDA approved laboratory. A certificate completed, signed and verified by an authorised representative of the USDA must accompany the consignment. Unlike previous Decisions made on aflatoxins, this was made under Article 23 of Regulation (EC) No 882/2004 and no corresponding domestic legislation was required to bring the Decision into force.

Similarly, almonds covered by the US Voluntary Aflatoxins Sampling Plan (VASP) are subject to 5% sampling while non VASP almonds remain at 100% sampling as provided for by [Commission Decision 2007/563/EC](#) further amending Decision 2006/504/EC.

The Food Standards Agency reported⁷ that the frequency of other controls on aflatoxins covered by Commission Decision 2006/504/EC as amended was discussed at the Commission in January. Having reviewed the information, it was agreed that the majority of provisions within the Decision should be kept as they are. However, consideration was given to reducing controls on peanuts from China and Egypt. In relation to products from Turkey, it was agreed that hazelnut oil should be added and the frequency of controls on pistachios should be increased in light of the high rate of non-compliance. This will be updated on a regular basis and circulated via the RASFF system. The Commission also expressed its intention to consolidate the Decision into a Regulation. It is anticipated that an updated guidance document on aflatoxins for enforcement authorities will be published by FSA in 2008.

⁶ Available at <http://www.food.gov.uk/foodindustry/imports/legislation/legislation>

⁷ [Chemical Contaminants Interested Parties Letter February 2008](#)

European Commission discussions on limits for ochratoxin A in liquorice and liquorice products and possible alternatives for maximum limits for ochratoxin A in certain spices appear to be continuing.

A Fusarium Forum⁸ was held at the Commission in January 2008 which raised several issues including the inconsistency of limits, the lack of data on toxicology for T2 and HT2 toxins and the lack of standardised analytical methods for T2 and HT2. The Joint Research Centre (JRC) is looking at validating methods for T2 and HT2, although significant further work is needed before standardising such methods. The Commission agreed to look into more detail for certain cases where the limits set for the cereal fractions could not be achieved but stated clearly that the limits set for Fusarium toxins would not be revised until 2009. There was an indication that deoxynivalenol (DON) may also be produced post harvest. It was suggested that this could be due to fungal stress upon drying but no definite reason was given. In particular, it was reported that both T2/HT2 and DON increased in beers. In the same document FSA also report the Commission noted that since soy for animal feed was found with high levels of zearalenone, then soy oil for human consumption may also be contaminated.

Codex draft maximum levels for aflatoxins in almonds, hazelnuts and pistachios are moving towards official Codex recognition and the Commission awaited a report from the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Draft maximum levels for ochratoxin A in cereals were also under consideration. Initial assessment from JECFA indicated that there is no difference in terms of public protection between a limit of 5ppb and a limit of 20ppb for ochratoxin A in wheat, barley and rye, although the final report is still awaited.

Commission Regulation (EC) No 1214/2007 of 20 September 2007 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical

⁸ *ibid*

nomenclature and on the Common Customs Tariff came into effect on 1 January 2008. The Regulation contains important information for all traders regarding the Combined Nomenclature (CN) codes and may affect commodities specified in the Commission Decisions on aflatoxins.

Other Contaminants

Lead, Cadmium, Mercury, Inorganic Tin, 3-Mcpd & Benzo(A)Pyrene

Commission Regulation (EC) No 333/2007⁹ laying down methods of sampling and analysis for the official control of levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs applied from 1 June 2007. Enforcement agencies are required to follow the sampling and analysis procedures in this regulation when taking official enforcement samples for the official control of levels of the above contaminants in foodstuffs.

Further limits for heavy metals were also actively under discussion during the year; Pb and Cd (but not Hg) limits were seen as needed for food supplements. Tea, coffee, herbs, algal products and spices are still under consideration. Simplification of Cd limits for fish was seen as desirable. There was lack of enthusiasm for application of limits to processed products. The limit for Cd in bivalve molluscs was discussed as some regions have high natural Cd levels although, of course, consumer protection remains paramount.

FSA reported¹⁰ a meeting of 11 April 2008 of the SCoFCAH (Tox)¹¹ where there was a consensus that limits are needed for lead and cadmium in food supplements because some very high levels had been reported (among them the data from the Government Chemist). Some Member States already have

⁹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:088:0029:0038:EN:PDF>

¹⁰ Food Standards Agency: Chemical Contaminants Interested Parties Letter May 2008 available from <http://www.foodstandards.gov.uk/foodindustry/regulation/europeleg/euupdates/contaminants0805>

¹¹ Standing Committee on the Food Chain and Animal Health

national legislation in place and as a compromise limits for lead, cadmium and mercury were proposed and agreed upon as follows:

Proposed maximum limits for food supplements as sold and as defined in Article 2 of Directive 2002/46/EC		
Metal	Maximum Limit	Comment
Pb	3.0 mg kg ⁻¹	
Cd	1.0 mg kg ⁻¹	non-seaweed based
	3.0 mg kg ⁻¹	supplements consisting exclusively or mainly of dried seaweed or of products derived from seaweed
Hg	0.1 mg kg ⁻¹	
The Commission has agreed that this legislation will apply from 1 July 2009		

The Commission is still considering introducing limits for benzo(a)pyrene in food supplements (especially herbal) and beverages and awaits an EFSA opinion. Issues surrounding PAH in smoked and dried fish from West Africa will be discussed in 2008. Following the FVO mission to India to investigate the contamination of guar gum with pentachlorophenol and dioxins, the Commission was not satisfied with the response of the Indian authorities, notably the proposed timetable for putting necessary safeguards in place to avoid a repeat occurrence. It therefore proposed its own measures, which include requiring all guar gum and guar gum-containing mixtures from India entering the EU directly or via a third country to be accompanied by certification to the effect that it is PCP-free. Testing of all incoming batches of guar gum for dioxin contamination was later suspended but vigilance on India Glycols Ltd products continues.

PCB limits for liver, including canned fish liver, currently excluded from 1881/2006 continue to be under scrutiny. The Commission continues to press ahead with limits for non-dioxin-like PCBs.

DIOXINS

Issues around a limit for dioxins in fish liver remain, despite a limit of 25 pg WHO-TEQ/g whole weight having been tentatively agreed at a Standing

Committee in December. Progress on the modification of the existing limits for dioxins and dioxin-like PCBs in liver, to be expressed on a whole weight rather than fat basis, continues to be hampered by the lack of contribution either in data or positions from most other Member States. However, the Commission has concluded that there is a good case for making the change and will put concrete proposals to the next meeting. Discussions on harmonised limits for non dioxin-like PCBs have continued although most Commission proposals have been rejected on the basis that they are too high to be meaningful. Discussions have begun with a view to setting limits for dioxins, total TEQ and non dioxin-like PCBs in baby foods.

Nitrate

In 2007 EFSA undertook a risk-benefit evaluation of nitrate in the diet and the results of this were expected during the first half of 2008. The outcome will be discussed by the Commission soon thereafter together with any necessary regulatory changes.

Acrylamide

Progress has been made on the proposed draft Code of Practice for the reduction of Acrylamide in Food¹².

Natural Mineral Water, Spring Water and Bottled Drinking Water

Among many other provisions the use of Ozone enriched air for the treatment of Natural Mineral Waters was further regulated by the Natural Mineral Water, Spring Water and Bottled Drinking Water (England), Regulations 2007¹³ with

¹² http://www.ciaa.be/documents/brochures/CIAA_Acrylamide_Toolbox_Oct2006.pdf

¹³ [The Natural Mineral Water, Spring Water and Bottled Drinking Water \(England\) Regulations 2007 No. 2785](#)

territorial equivalents^{14, 15, 16} that revoked and re-enacted with changes the 1999 regulations. This is a major consolidation and simplification of provisions that were previously scattered among various national and European measures. FSA guidance notes to these regulations were consulted on in 2007 and issued in 2008¹⁷

Food Contact Materials

A useful summary of European and national legislation in this area is given at http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm and information on reference materials and analytical methods is available from the [Community Reference Laboratory for food contact materials](#).

In the UK, regulation in the field of food contact materials follows European law and falls into five main sets of regulations:

- the Materials and Articles in Contact with Food Regulations ('Generic Regulations', including e.g. regenerated cellulose film),
- the Plastic Materials and Articles in Contact with Food Regulations ('Plastics Regulations'),
- the Ceramic Articles in contact with Food Regulations,
- the Plastic Materials and Articles in Contact with Food (Lid Gaskets) Regulations ('Lid Gaskets Regulations') and
- Plastics derived from recycled plastics.

The Generic and Ceramic Regulations

¹⁴ [The Natural Mineral Water, Spring Water and Bottled Drinking Water \(Scotland\) Regulations 2007 No. 435](#)

¹⁵ [The Natural Mineral Water, Spring Water and Bottled Drinking Water \(Wales\) Regulations 2007 No. 3165 \(W. 276\)](#)

¹⁶ [The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations \(Northern Ireland\) 2007 No. 420](#)

¹⁷ [Food Standards Agency - Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 2007 Guidance Note](#)

During the period of this report the 'Generic Regulations' were remade as [the Materials and Articles in Contact with Food \(England\) Regulations 2007](#) with territorial equivalents¹⁸ to provide for the enforcement in the UK of [Commission Regulation \(EC\) No. 2023/2006](#) (the "GMP Regulation"), on good manufacturing practice for materials and articles intended to come into contact with food. The regulations also implement [Commission Directive 2007/42/EC](#) relating to materials and articles made of regenerated cellulose film intended to come into contact with food ("the RCF Directive"). The English Regulations came into force for the purposes of regulations 5, 7 and 14(3), on 1 August 2008; and for all other purposes, on 29 October 2007. They revoked The Materials and Articles in Contact with Food (England) Regulations 2005 (SI 2005 No. 898) as amended in their entirety. The underpinning European measure remains the framework Regulation (EC) No. 1935/2004 and provisions relating to prescribed methods and procedures for checking compliance with migration limits and for vinyl chloride monomer also remain. The inclusion of an Annex specifically on GMP for printing inks (applied to the non-food contact side of a material or article) follows the widespread contamination of foodstuffs throughout the EU by isopropylthioxanthone (ITX) caused by set-off from the non-food contact surface. Affected foodstuffs included fruit juices and infant and follow-on formulae. All EU countries were affected. Although there was no health risk arising from this incident, the presence of the chemical was undesirable and preventable.

Regulation 2(4) allows references to EC law to be construed as references to the instrument or specified part of it as it may be amended from time to time. The Legislative and Regulatory Reform Act 2006 makes such ambulatory references permissible where it seems necessary or expedient to the Secretary of State. The ambulatory references specified in the Regulations are to the GMP Regulation and to two Annexes to Directives which contain lists of chemical compounds and technical specifications that are subject to

¹⁸ [The Materials and Articles in Contact with Food \(Scotland\) Regulations 2007 No 471](#)
[The Materials and Articles in Contact with Food \(Wales\) 2007 No 3252 \(W. 287\)](#)
[The Materials and Articles in Contact with Food \(Northern Ireland\) Regulations 2007 No 434](#)

regular updating and amendment by the European Commission. Use of the ambulatory references will obviate the need to introduce a new SI each time these Annexes or the GMP Regulation are updated and thus it will be important to track European measures to ensure correct interpretation of the UK legislation.

It was also noted¹⁹ that paragraph 1(5) of Schedule 3 to the Ceramic Articles in Contact with Food (England) Regulations (S.I. 2006/1179) was defectively drafted. The Regulations were made by the then Secretary of State for Trade and Industry, but the Food Standards Agency subsequently took over the administration of this instrument and undertook to correct the defect. Regulation 22 of the Materials and Articles in Contact with Food (England) Regulations 2007 makes this correction.

The Regulations also make consequential amendments to the Plastic Materials and Articles in Contact with Food (England) (No.2) Regulations 2006 (S.I. 2006/2687) and the Food Safety (Sampling and Qualifications) Regulations 1990 ([S.I. 1990/2463](#)) (*regulations 23 & 24*).

The Government Chemist made an extensive response to the consultation that preceded the regulations. Included were comments on:

- the need for further guidance on GMP as legislation only provides detailed rules in relation to printing inks;
- the replacement of rigidly prescribed methods with clear performance criteria which must be met by any analytical procedure employed;
- the need for the Agency and local food authorities to publish the results of their monitoring work; and
- positive recognition of the whole range of circumstances in which samples may be submitted to the Government Chemist, whilst noting that additional costs may arise.

¹⁹ [Explanatory Memorandum to the Materials and Articles in Contact with Food Regulations \(England\) 2007](#)

The Plastics and Lid Gaskets Regulations

The 'Plastics Regulations' were again remade in 2007 and also stem ultimately from the framework Regulation (EC) No. 1935/2004 although plastics are regulated by Directive 2002/72/EC. The explanatory memorandum²⁰ and impact assessment provide a readable background to the development of the regulations.

The remaking was necessary because of [Commission Directive 2007/19/EC](#) which amended Directive 2002/72/EC. This amendment, the fourth to the 2002 Directive, routinely updates the lists of monomer substances and additives permitted for use in the manufacture of food contact plastics and lays down any necessary conditions for their safe use. The changes to these lists of substances are made periodically when the European Food Safety Authority has revised an existing opinion or issued a new one on the safe use of a substance. Other amendments that the 2007 Directive makes to the original 2002 Directive provide

- clarity about the detail required in compliance declarations that must accompany goods being traded up to the retail stage;
- distinction between the terms 'plastic multi-layer' and 'plastic functional barrier' and defines the function of such a barrier;
- removal of the suspension imposed on the use of azodicarbonamide as a foaming agent in the plastic in favour of an outright ban;
- clarification that gaskets used to seal glass food jars are subject to the rules laid down in the 2002 Directive whilst providing time for manufacturers to obtain authorisation for the use of the additives they employ in making these gaskets;
- supersession of Commission Regulation (EC) No 372/2007 which laid down transitional (within the time period 23 April 2007 – 30 June

²⁰ [Explanatory memorandum to the Plastic Materials and articles in Contact with Food \(England\) Regulations 2008](#)

2008) migration limits for plasticisers in gaskets in lids intended to come into contact with food;

- for the use of a new food stimulant (50% ethanol) to test more accurately for chemical migration into milk products;
- for the use of a fat reduction factor to calculate migration into fatty food types more accurately;
- the dates from which compliant goods may be traded and from which non-compliant goods may not be manufactured or imported into the Community;
- amendments to Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs; and
- provisions for epoxy derivatives (BADGE, BDGE and NOGE) and revised provisions for primary aromatic amines, epoxydised soybean oil, and some phthalates.

The draft was made into law by the [Plastic Materials and Articles in Contact with Food \(England\) Regulations 2008 No 916](#) with territorial equivalents²¹.

The English regulations came into force on 1 May 2008 for all purposes except the revocation of The Plastic Materials and Articles in Contact with Food (Lid Gaskets) (England) Regulations 2007, a temporary measure extended only until 1 July 2008. The Plastic Materials and Articles in Contact with Food (England) (No.2) Regulations 2006 were revoked as was Regulation 24 of the 2007 'Generic Regulations' (dealing with method of testing the capability of materials or articles to transfer constituents, and methods of analysis).

²¹ [The Plastic Materials and Articles in Contact with Food \(Scotland\) Regulations 2008 No. 127](#)
[The Plastic Materials and Articles in Contact with Food \(Wales\) Regulations 2008 No.1237 \(W.124\)](#)
[The Plastic Materials and Articles in Contact with Food \(Northern Ireland\) Regulations 2008 No.167](#)

Ambulatory references to the latest amendment to European Directives are again employed to avoid remaking the regulations on foot of e.g. changes to lists of compounds (see above) so that scrutiny of forthcoming European Directives in the food contact area will be required to ensure up to date interpretation of the Regulations. For example Commission Directive 2008/39/EC of 6 March 2008 amended Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food, with an updated list of monomers and additives; see:

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:063:0006:0013:EN:PDF>.

Use Of Recycled Plastics

The use of recycled material for the production of plastics was the subject of a Regulation introduced by the Commission, [Regulation 282/2008 of 27 March 2008](#), close to the end of this monitoring period. It deals with recycled plastic material other than from starting materials obtained from chemical depolymerisation or from offcuts used on the manufacturing site. The finished products also remain subject to 2002/72/EC.

Efsa Positive Lists

Before a substance is authorised to be used in food contact materials and is included in a positive list EFSA's opinion on its safety is required. EFSA has published²² opinions on a further (17th) list of compounds and, for most, has recommended maximum migration limits (from 0.05 – 5 mg/kg) in food. An 18th list was published in March 2008. A searchable index of such opinions and lists is available at:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm

Food Additives

Interest in food additives was maintained with revised provisions in traditional areas such as preservatives, sweeteners, antioxidants and extraction solvents and proposals to extend regulatory control of enzymes and flavourings. Research on the more subtle effects of some additives on children's' behavior also came under scrutiny in the period of this review.

The Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (England) Regulations 2007 No. 1778 were published in June and came into force on 25 July 2007 ([OPSI text](#)), with territorial equivalents²³. They amended the 1995 Miscellaneous Additives Regulations to insert definitions of flavouring and food supplement, to prohibit a range of additives²⁴ in 'jelly cups' and to amend extensively certain measures relating to preservatives and antioxidants. The sweetener E968 erythritol was listed as permitted and other amendments made including updating of references to recently amended European law²⁵. A defect in the Regulations, the entry for E473 Sucrose Esters of Fatty Acids in Schedule 8, should have been listed in Part 4 (dietary foods for special medical purposes) rather than Part 3 (permitted in weaning foods for healthy children), and was rectified by the [Miscellaneous Food Additives \(Amendment\) \(England\) Regulations 2008, No 42](#).

²² http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178675761369.htm

²³ [MFA&SiF\(A\)\(Scotland\) Regulations 2007](#)
[MFA&SiF\(A\)\(Wales\) Regulations 2007](#)
[MFA&SiF\(A\)\(Northern Ireland\) Regulations 2007](#)

²⁴ E400, E401, E402, E403, E404, E406, E407, E407a, E410, E412, E413, E414, E415, E417, E418 and E440, alginates, agar, carrageenan, processed eucheuma seaweed, a range of gums and pectins. The Commission previously banned the food additive E 425 konjac, konjac gum or konjac glucomannan in jelly mini-cups - see <http://www.food.gov.uk/news/newsarchive/2004/apr/jellysweetseubannews>

²⁵ Directive 2006/52/EC and Directives 2006/129/EC and 2006/128/EC, which amend Directives 96/77/EC and 94/31/EC, to set out purity criteria for the seven newly approved additives that have been permitted by way of Directive 2006/52/EC, and which also amend

A University of Southampton study²⁶ commissioned by the Food Standards Agency was published in 2007. The findings suggest that a mixture of some food colours (sunset yellow E110, quinoline yellow E104, carmoisine E122, allure red E129, tartrazine E102 and ponceau 4R E124) and benzoate based preservative could be linked to an adverse effect on the behaviour of hyperactive children. EFSA completed an initial review of the study and decided that a further detailed assessment was required. This concluded that the findings of the study cannot be used as a basis for altering the ADI of the respective food colours or sodium benzoate. The FSA Board^{27,28} agreed to advise UK Ministers that there should be voluntary action by manufacturers in the UK to remove the six artificial colours by 2009, with parallel action in the EU to phase them out over a specified period.

A Commission proposal²⁹ on food enzymes noted the scope of EU legislation (Directive 89/107/EEC) only covers enzymes used as food additives. Some enzymes are not regulated at all while others used as processing aids are regulated under diverse MS domestic legislation. The proposal provides for a Community list of approved (safe) food enzymes, conditions of use and rules on labelling. A similar proposal³⁰ was made to clarify and modernise legislation on flavourings, and a third³¹ to establish a common authorisation procedure for food additives, food enzymes and food flavourings.

The EFSA Panel on additives, flavourings, processing aids and materials in contact with food (AFC) is working on a systematic evaluation of the safety of flavouring substances currently in use in the European Union. A programme

the purity criteria for a number of the currently permitted miscellaneous additives and sweeteners.

²⁶ McCann D, Barrett A, Cooper A, Crumpler D, Dalen L, Grimshaw K, Kitchen E, Lok K, Porteous L, Prince E, Sonuga-Barke E, Warner JO & Stevenson J (2007). Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomised, double-blinded, placebo controlled trial. *Lancet*, 370, 1560-1567.

²⁷ Board Paper FSA 08/04/04 10 April 2008

<http://www.food.gov.uk/multimedia/pdfs/board/fsa080404a.pdf>

²⁸ Minutes of the Board meeting 10 April 2008

<http://www.food.gov.uk/multimedia/pdfs/board/boardmins080410.pdf>

²⁹ COM (2007) 670 final of 24.10.07

³⁰ COM (2007) 671 final of 24.10.07 see [European law on flavourings](#)

³¹ COM (2007) 672

for their evaluation is laid down by Regulation (EC) No. 2232/96 and Regulation (EC) No. 1565/2000. Informed by this work, the Commission will establish a positive list of flavouring substances authorised for use in the EU.

The Member States have notified about 2,800 flavouring substances that may, in accordance with Directive 88/388/EEC, be used in and on foodstuffs marketed in their territory. These 2,800 flavouring substances have been compiled by the Commission into a register. EFSA has divided these flavouring substances into 48 groups for evaluation. Among flavourings listed in the register there are many substances which occur naturally in animal and vegetable products as well as artificial flavouring substances.

In order to confirm that their use is safe, EFSA are looking at intake levels, absorption, metabolism and toxicity of individual substances in the human body. Whilst undertaking these evaluations, EFSA has in several cases identified data gaps and is requesting additional information. The type of data missing varies from production volumes to information on toxicity that might require additional research and testing in vitro and in vivo.

Recently one substance, 2-methyl-1,3-butadiene (isoprene), has been identified where there are adequate data to question its safety given its genotoxic potential and carcinogenic effects in experimental animals. Given the available data on possible risks, EFSA finds that isoprene should not go forward for further evaluation.

EFSA aimed to complete the evaluations of all the substances in the Register, for which adequate data have been received, by April 2008. The first set of evaluations dealt with acetals and a further set of three EFSA opinions was issued in March on esters, pyrazine derivatives, phenyl-substituted compounds and phenethyl related structures.

In March a proposal was announced for a recast directive of the European Parliament and Council on the approximation of the laws of the Member

States on extraction solvents used in the production of foodstuffs and food ingredients.

Food Allergens

Following advice from the European Food Safety Authority, the Commission extended the list of 12 potential food allergens that must be highlighted in prepacked food labelling if the product is formulated to contain them. Thus [Directive 2006/142/EC](#) updated Annex IIIa of Directive 2000/13/EC to include lupin and molluscs³² (gastropods, bivalves or cephalopods), and products obtained from them, promulgated by the (now revoked) Food Labelling (Declaration of Allergens) (England) Regulations 2007 No. 3256 with territorial equivalents.

It was thought probable that some ingredients or substances derived from ingredients listed in Annex IIIa may not, under specific circumstances, trigger adverse reactions. Thus in order to minimise the potential for confusion³³, after the inception of allergen labelling the possibility was envisaged of excluding such material (e.g. fully refined oils) from labelling requirements provided their non-allergenicity was scientifically established. Thus Commission Directive 2005/26/EC established a list of food ingredients or substances provisionally excluded from the need for labelling highlighting until 25 November 2007. [Directive 2007/68/EC](#) of 27 November 2007 confirms the extension of Annex IIIa and makes permanent the list of exemptions. The final list differs from the provisional one, for example egg lysozyme and albumin, previously provisionally exempt do not appear in the permanent exemption list. Owing to a delay in making the Directive a transition period until May 2009 is allowed. A consultation on domestic regulations to implement the above ended on 14 March 2008. The draft regulations and consultation responses

³² The occurrence and allergenicity of lupin and mollusc are briefly described in the [explanatory memorandum to the regulations](#)

³³ Gowland, H. personal communication

are available [on the FSA website](#) and the Food Labelling (Declaration of Allergens) (England) Regulations 2008 No. 1188 [\(text\)](#) with territorial equivalents³⁴ came into force on 31 May 2008, revoking the 2007 regulations.

The House of Lords published a major investigation into allergy³⁵ and a Government response was published³⁶ in November 2007.

See also under Labelling below.

Food Hygiene

In May 2007 FSA³⁷ began widespread consultation on a proposal arising from the European Commission's *Strategic Review of Better Regulation in the European Union*, which includes a proposal to reduce the administrative burdens on business by 25% by 2012. The proposal would exclude food business operators with fewer than ten employees predominantly selling food to the final consumer, from the requirement to put in place food safety management procedures based on the HACCP principles, recognised world-wide as a tool for helping food businesses control hazards to food safety. The proposal drew widespread criticism from consumer groups, the vast majority of local authorities and most industry respondents to varying degrees.

The fundamental objection raised by respondents was that the proposal was based on numbers of employees and on turnover and not on risk. The consensus of opinion was that risk must be the main issue in considering what food safety procedures businesses undertook. It was noted that some small food businesses (i.e. those that might be exempted from HACCP based

³⁴ [....\(Scotland\) 2008 No. 180](#)
[..... \(Wales\) 2008 No. 1268 \(W.128\)](#)
[..... \(Northern Ireland\) 2008 No. 198](#)

³⁵ <http://www.publications.parliament.uk/pa/ld200607/ldselect/ldscstech/166/166i.pdf>

³⁶ <http://www.official-documents.gov.uk/document/cm72/7255/7255.pdf>

³⁷ The consultation documents and a summary of the responses are available at:
<http://www.food.gov.uk/consultations/ukwideconsults/2007/EC852consultation>

procedures were the proposal to be adopted) do undertake high risk activities and have been responsible for food poisoning cases.

At the time of writing (July 2008) insufficient support from Member States for the proposal has meant that it has stalled. It seems unlikely that it will progress further this year.

In October 2007 the FSA³⁸ issued a consultation on draft Food Hygiene Regulations dealing with definitions of Community legislation, the time gap between slaughter and mincing of chilled meat and other slaughterhouse issues. The key proposals were:

- to amend the list of definitions of Community legislation in the Food Hygiene (England) Regulations 2006;
- to disapply the criteria in paragraph 2(b), Chapter III, Section V, Annex III of Regulation (EC) 853/2004 regarding the number of days between slaughter and the mincing of chilled meat;
- to allow certain slaughterhouses formerly classified as low throughput to be exempted from the requirement to have facilities for detained meat and facilities for cleansing and disinfection of livestock vehicles;
- to prescribe the format for a special health and identification mark to be used on carcasses of animals subject to emergency slaughter outside a slaughterhouse and on the meat derived from such carcasses and
- to provide a legislative framework for carrying out a pilot project at certain low throughput approved game handling establishments.

At the time of writing (July 2008) the draft regulations had not been made law but are expected later in 2008.

³⁸ The consultation documents and a summary of the responses are available at: <http://www.food.gov.uk/consultations/consulteng/2007/hygieneenglandamend08>

MARINE BIOTOXINS

In 2007 EFSA was asked by the European Commission (EC) to assess the current European Union (EU) limits for various marine biotoxins in relation to human health and the methods of analysis used to detect these toxins. This is the first in a series of nine opinions on the various biotoxins and it addresses one group, okadaic acid (OA) and related toxins that together form the group of OA-toxins.

EFSA's CONTAM Panel has assessed the available data and identified for OA-group toxins a level at which most consumers, even those eating a large portion of shellfish, would be unlikely to get shellfish poisoning. The Panel has also highlighted shortcomings in current animal testing methods and made recommendations for future work on alternative methods. OA-group toxins are usually produced by a type of plankton in the sea. These toxins can contaminate shellfish, notably bivalve molluscs such as oysters, mussels, scallops, and clams. Contaminated shellfish may cause diarrhetic shellfish poisoning (DSP). DSP can also be caused by other toxins, not only OA-toxins. OA-group toxins levels are monitored in Europe. Food businesses must ensure that bivalve molluscs placed on the market for human consumption do not exceed the current European regulatory limit of 160 µg of OA equivalents per kilogram shellfish meat. By looking at the available human and other toxicological data, EFSA's CONTAM Panel decided to establish an acute reference dose (ARfD) for OA-group toxins, given their acute toxicity. The ARfD was identified by studying available evidence on the lowest levels at which the toxins led to human illness and by applying an uncertainty factor. This resulted in an ARfD of 0.3 µg OA equivalents per kilogram bodyweight. The Panel noted that the dietary exposure of a 60 kg adult consuming a large portion of shellfish meat (400 g) contaminated at the current EU regulatory limit would exceed the ARfD by approximately 3-fold and is close to the lowest level at which the toxins could lead to illness. This intake would be expected to have an effect on susceptible consumers. To avoid exceeding the Panel's

ARfD a 400 g portion of shellfish would need to contain no more than 45 µg OA equivalent per kg shellfish meat.

The Panel also considered the current methods of analysis. Tests involving mice and rats are currently the officially prescribed reference methods in the EU for identifying OA-group toxins. The Panel concluded that both methods have shortcomings such as limited capability to detect OA-group toxins at the current EU regulatory limit or below that. Alternative biomolecular and chemical methods have the greatest potential to replace the animal tests and to detect OA-group toxins below the current EU regulatory limit. However, according to EU legislation alternative (presumably chemical) methods of determining marine biotoxins have to be validated following internationally recognised protocols. The Panel noted that validation by interlaboratory trials should be a long-term objective.

The Panel made a series of recommendations, for example to improve Member States (MS) reporting systems and sampling procedures; and to strengthen databases held on shellfish consumption. The need for further toxicological data was highlighted, as were recommendations on methods of analysis. The opinion and recommendations will help inform further thinking about methods of analysis at European level by the EC and MS.

A FSA consultation³⁹ of March 2008 proposed that, from 5 May 2008, HPLC (High Performance Liquid Chromatography) will be introduced in the UK. This is in place of the MBA (mouse bioassay) for the detection of paralytic shellfish poisoning (PSP) toxins in mussels submitted as part of the statutory biotoxin monitoring programme. The proposal included an interesting rare example of a decision rule that cites the upper bound of the mean result plus expanded uncertainty as the criterion to close a shellfish bed.

³⁹ [Food Standards Agency - High Performance Liquid Chromatography for the detection of paralytic shellfish poisoning in England](#)

Pesticides

The principal domestic regulations remain the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff) (England and Wales) Regulations 2005⁴⁰. These were amended in 2007 by the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff) (Amendment) Regulations 2007 No. 971, amending the 2006 Regulations by deleting and changing entries on specific pesticides to reflect changes in EU legislation. These were themselves amended by the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff) (England and Wales) (Amendment) (No. 2) Regulations 2007 No. 2083, ([text](#)). The Regulations substitute or insert new residue definitions for certain pesticides in Schedule 1 to the principal Regulations and new maximum residue levels for certain pesticides in Schedule 2 to the principal Regulations. A consolidated version of this Schedule and Schedule 1 (which lists for each pesticide the specific compound(s) which comprise(s) the pesticide residue) are posted by the Pesticides Safety Directorate⁴¹ in an easy to read format, on its website which also lists all the UK regulations including territorial equivalents⁴².

The explanatory memorandum⁴³ published with the regulations points out that the current system of transposing Commission Directives by Statutory Instrument will end when EC Regulation 396/2005 comes fully into force in the near future. EC Regulation 396/2005 will provide for a fully integrated EC MRLs regime, avoiding the need for member States to transpose via National legislation. Although the framework regulation is in place, work on the first four Annexes to Regulation 396/2005 must be completed before it comes fully into force. On current estimates this work will be concluded in time for the Regulation to come into force in mid 2008.

⁴⁰ S.I. 2005/3286, as amended by S.I. 2006/985, S.I. 2006/1742 and S.I. 2006/2922.

⁴¹ <https://secure.pesticides.gov.uk/MRLs/>

⁴² http://www.pesticides.gov.uk/food_safety.asp?id=548

⁴³ http://www.opsi.gov.uk/si/si2007/em/uksiem_20072083_en.pdf

Commission Recommendation 2007/225/EC of 3 April 2007 concerning a coordinated Community monitoring programme for 2007 to ensure compliance with maximum levels of pesticide residues in and on cereals and certain other products of plant origin and national monitoring programmes for 2008 specifies a broad range of pesticides and frequency of monitoring across the Community during 2007-2009 and achieves this through co-ordination of National Monitoring Programmes across the Community.

Commission Recommendation 2008/103/EC of 4 February 2008 concerning a coordinated Community monitoring programme for 2008 to ensure compliance with maximum levels of pesticide residues in and on cereals and certain other products of plant origin and national monitoring programmes for 2009 gave the rationale for and a list of pesticide and matrix combinations that MS should sample and analyse to allow using these data for the estimation of actual dietary exposure and allow with a certainty of more than 99 %, the detection of a sample containing pesticide residues above the limit of determination (LOD), provided that not less than 1 % of products of plant origin contain residues above that limit. Commission Decision 2008/105/EC of 11 February 2008 amended Decision 2004/432/EC on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC.

Sudan Dyes

The presence of illegal dyestuff Sudan I and related compounds in chilli powder first identified in France, in May 2003, led to a number of product recalls in the UK and other Member States. In February 2005 the UK experienced the largest recall of food products following the discovery that an adulterated batch of chilli powder had been supplied to a manufacturer of Worcestershire sauce (Premier Foods) in 2002. The FSA commissioned an

independent review of the incident which reported in September 2007⁴⁴. The review, chaired by Professor Douglas Georgala, made recommendations directed towards all sectors, covering four main areas: incident prevention, incident handling, communications and relationships. A number of actions already taken by the Agency since the incident included the setting up of a Food Incidents Task Force, which published guidance on prevention and handling in March 2007. A national food fraud database has also been developed, providing local authorities with an effective resource to assist with their investigations. The Agency also strengthened its early warning systems through closer working with the European and World Health Organisation incident networks.

The Government Chemist submitted his response to the Sudan I incident for consideration at the FSA open meetings. The GC's overall recommendation was that the Food Standards Agency (FSA) should foster a marketplace for a rapid response from laboratories in such circumstances so that decisions taken can be best informed by good analytical science for example based on the international harmonised protocol that exists for single laboratory validation.

Veterinary Residues

Veterinary residues in animals are subject to control at European level⁴⁵ delegated to Defra in the UK and its agencies. In April 2007 the Commission issued a proposal for a new legal framework for Maximum residue Limits (MRLs) for veterinary residues, titled 'Regulation of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal

⁴⁴ [FSA 07/09/06 Board paper and Report of the Sudan I Review Panel](#)

⁴⁵ <http://europa.eu/scadplus/leg/en/lvb/l21152.htm>

origin, and repealing Regulation (EEC) No 2377/90⁴⁶. The current legal framework for MRLs has led to particular problems:

- Availability of veterinary medicines has decreased to an extent that creates adverse effects for public and animal health and animal welfare;
- International standards supported by the EU cannot be included in Community legislation without a new scientific assessment by the European Medicines Agency;
- Control services of Member States have no points of reference in particular for substances detected in food from third countries;
- The current legislation is difficult to understand.

The proposal will:

- Improve availability of veterinary medicinal products for food producing animals in order to ensure animal health and welfare and avoid illegal use of substances;
- Simplify the existing legislation by enhancing readability of the provisions on established MRLs for the end-users (i.e. animal health professionals, control competent authorities in Member states and third countries);
- Provide clear references for the control of residues of pharmacologically active substances in foodstuffs to improve consumer health protection and the functioning of the Single Market;
- Clarify the Community procedures establishing Maximum Residues Limits (MRLs) by ensuring consistency with international standards.

At the time of writing (July 2008) the proposal awaited its first reading at the Council of Ministers⁴⁷.

⁴⁶ [COM \(2007\) 194 Final 2007/0064 \(COD\) Brussels 17.4.2007](#)

The Commission also made regulations amending Regulation 2377/90 to permit up to maximum residue limits the veterinary medicines firocoxib⁴⁸, monensin, flubendazole and lasalocid⁴⁹ and tylvalosin⁵⁰ in foodstuffs of animal origin from January 2008. Maximum concentrations of the veterinary medicine Avilamycin in various tissues of porcine, rabbit and poultry were proposed (effective from 18 November 2007) by Commission Regulation 1064/2007⁵¹. A provisional maximum residue limit was established for the veterinary medicinal product gamithromycin⁵² in foodstuffs of animal origin.

CONSUMER CHOICE & PREVENTION OF FRAUD

LABELLING

The most significant development during the period of interest was the initiation by the Commission of a review of food labelling. This is unlikely to happen again for another 20 years and it is therefore important that consumers and fair traders derive maximum benefit from the outcome. Current EU food labelling rules have evolved over many years and are complex, being subject to many different pieces of legislation. A major aim of the review was to simplify the rules and reduce burdens on industry, without loss of consumer information or protection. In preparation for the review the

⁴⁷ <http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=2&procnum=COD/2007/0064>

⁴⁸ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:294:0011:0013:EN:PDF>

⁴⁹

[http://www.agriculture.gov.ie/feedingstuffs/legislation/Animal_Health/EU_Legislation/CommReg1055_2006\(Amends2377_90\).pdf](http://www.agriculture.gov.ie/feedingstuffs/legislation/Animal_Health/EU_Legislation/CommReg1055_2006(Amends2377_90).pdf)

⁵⁰ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:303:0006:0008:EN:PDF>

⁵¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:243:0003:0005:EN:PDF>

⁵² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:060:0018:0020:EN:PDF>

FSA held a Board workshop⁵³ in late 2006 where common themes were developed including the need for core mandatory information, based on key principles such as 'safety' and 'clearly understandable'; the right of the consumer to have access to core information for all food, including those sold loose; the need for clear, simple, consistent and transparent legislation; the need to ensure clarity, perhaps by means of a standard panel. Enforcement was seen as a key issue.

Following extensive consultation the Commission published its proposal on 30 January 2008 for a new regulation 'on the Provision of Food Information to consumers' bringing together legislation on general and nutrition labelling into a single text with an explanatory memorandum⁵⁴. The key elements of the proposal are:

- To ensure that consumers have, in a legible and understandable manner, the essential information they need to make informed purchasing choices.
- the draft Regulation sets down general principles for food labelling including requirements that the label is legible (print size of at least 3 mm), clear and accurate and that the presentation of voluntary information does not detract from the mandatory information;
- To promote healthier diets by requiring pre-packaged food to display key nutritional information on the front of the pack. General requirements on how nutrition information should be displayed on food labels are also set out, although there is room for Member States to promote additional national schemes provided they do not undermine the EU rules.
- the proposal requires that the energy, fat, saturated fat, carbohydrates with specific reference to sugars and salt content per 100 ml/g or per portion of the product are displayed clearly on the front of the packet. In

⁵³ <http://www.foodstandards.gov.uk/multimedia/pdfs/fsaboardlab.pdf>

⁵⁴ http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/proposal_regulation_ep_council.pdf

addition, the proportion of these elements to the reference intakes (e.g. Recommended Daily Allowance) must be indicated (similar to the GDA declaration used by some UK retailers) for mandatory nutrients. The proposal is silent on where on pack this should be;

- For public health reasons, the draft Regulation extends the current requirements for allergen labelling to cover non pre-packed food, including food sold in restaurants and other catering establishments.

The FSA began a consultation on the broad issues⁵⁵ and there were subsequent Board discussions (e.g. front of pack nutrition labelling⁵⁶). The European legislation may not be finalised until 2010 or later.

In the meantime, to address the confusion that can arise with multiple amendments, Commission Directive 94/54/EC of 18 November 1994 on the compulsory labelling of certain particulars on food was codified in Commission Directive 2008/5/EC of 30 January 2008⁵⁷. This covers, for example, inert gases used in packaging, added sugars and sweeteners, foods containing aspartame ('contains a source of phenylalanine'), foods containing more than 10 % added polyols ('excessive consumption may produce laxative effects') and foods containing glycyrrhizinic acid or its ammonium salt.

In October 2007 the FSA began consulting on a range of labelling guidance documents and will subsequently publish updated versions of the guidance on:

- Clear food labelling⁵⁸;
- Country of origin labelling⁵⁹; and

⁵⁵ [Food Standards Agency - A framework for the provision of mandatory food information and labelling requirements for food sold loose](#)

⁵⁶ [Board Paper FSA 08/04/05 10.4.2008](#)

⁵⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:027:0012:0016:EN:PDF>

⁵⁸ [Published Guidance Clear Food Labelling](#)

- Criteria for the use of the terms fresh, pure, natural etc in food labelling⁶⁰.

There was a consultation on the UK National Food Labelling Provisions⁶¹ – the labelling provisions in question are:

- Provident Societies
- Charities
- Fortified Flour
- Added Ingredients
- Manner of Presentation flexibility
- Flour Confectionery
- Minor accompaniment (e.g. sachets of tomato sauce in a restaurant).

Lastly, Commission Decision 2008/35/EC of 8 January 2008⁶² was delivered concerning a draft Regulation from the Hellenic Republic. The Greek authorities sought to establish compulsory domestic law requiring labelling of bakery products from frozen dough with the date of production and the origin of the frozen dough. The Commission disallowed this as a barrier to trade emphasising the care needed by MS in domestic legislation on labelling.

Composition

FSA, to ensure the UK industry benefits from the ability to standardize the protein content of preserved milk, began consulting on Condensed Milk and Dried Milk (Amendment) Regulations 2008. These will implement Directive

⁵⁹ [Guidance on country of origin consultation](#)

⁶⁰ [Published guidance Criteria for the use of the terms fresh, pure, natural etc. in food labelling](#)

⁶¹ [Food Standards Agency - UK National Food Labelling Provisions](#)

⁶² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:008:0013:0014:EN:PDF>

2007/61/EC. They refer to Directive 79/1067 for methods of analysis (e.g. for fat, lactic acid ...) and bring in Regulation 1925/2006 for the addition of vitamins and minerals. The regulations came into force in England in February 2008⁶³ with territorial equivalents⁶⁴. These Regulations amend the definitions of partly dehydrated milk and totally dehydrated milk in the 2003 Regulations and for example define milk retentate, which is the product obtained by concentrating milk protein by ultra filtration of milk, and milk permeate, which is the product obtained by removing milk proteins and milk fat from milk, by ultra filtration. The levels of dry matter, moisture content, fat, sucrose, lactic acid and lactates and phosphatase activity in the designated products are to be determined in accordance with the methods set out in Directive 79/1067.

A further proposed codification (annotated document for measures that have had up to 10 amendments) was COM (2007)848 final of 20.12.07 on aromatized wines, drinks and cocktails, such as vermouth, sangria etc⁶⁵.

The addition of starch and protein to meat products and preparations came under scrutiny in the period under review. Regulation 5 of the Meat Products Regulations 2003 (MPR 2003) exempts from disclosure in the name of the food the addition of starch and protein to cuts of meat or cured meat⁶⁶ if it was added for 'technological reasons'. The phrase 'technological reasons' was never defined and practically all such additions could be (and were) claimed to be for technological reasons. Moreover, labelling regulations *may* have overridden the exemption. Repeal of Council Directive 77/99/EEC prompted the review of these provisions of regulation 5 of MPR 2003.

⁶³ [The Condensed Milk and Dried Milk \(England\) \(Amendment\) Regulations 2008 No. 85](#)

⁶⁴ [The Condensed Milk and Dried Milk \(Wales\) \(Amendment\) Regulations 2008 No. 137 \(W. 19\)](#)
[The Condensed Milk and Dried Milk \(Scotland\) Amendment Regulations 2008 No. 12](#)
[The Condensed Milk and Dried Milk \(Amendment\) Regulations \(Northern Ireland\) 2008 No. 42](#)

⁶⁵ [EUR-Lex - 52007PC0848 - EN](#)

⁶⁶ Meat with the appearance of a cut, joint, slice, portion or carcase of meat or cured meat.

The FSA began a consultation⁶⁷ in July 2007 on the draft regulations, guidance as to their implementation and on best practice advice on the general labelling of added ingredients in meat products which have the appearance of 'plain' meat. A threshold (perhaps 1%) above which disclosure in the name of the food would be required was suggested but in the event there was insufficient support for this.

The regulations came into force in England on 6 April 2008⁶⁸ with territorial equivalents⁶⁹ but at the time of writing (July 2008) the guidance has yet to be published although it is expected in the autumn. The *draft* guidance states:

5.15 Regulation 5(2)(b) of the MPR 2003 (and its equivalents in the devolved administrations) requires added ingredients in certain meat products to be declared in the name of the food unless they are exempted from this requirement by Schedule 3 of the MPRs. However, in line with the new EU rules, regulation 5(2)(b) no longer applies to added starch and protein and the related reference to starch and protein added for technological purposes has been removed from Schedule 3 of the MPR 2003. Therefore, there is no longer a specific requirement to declare added starch and protein in the name of the food for meat products irrespective of why they are used.

5.16 However, the FSA 1990 and the general food labelling rules of the Food Labelling Regulations 1996 (as amended) relating to the name of food provisions will continue to apply to all meat products including those with added starch and/or proteins. Therefore, in the absence of any name prescribed by law for the food or customary name which is used, any added starch or protein would need to be declared in the name of the food of meat products if not to do so would mislead the

⁶⁷ [Food Standards Agency Consultation - Meat Products \(England\) \(Amendment\) Regulations 2008 and Guidance](#)

⁶⁸ [The Meat Products \(England\) \(Amendment\) Regulations 2008 No. 517](#)

⁶⁹ [The Meat Products \(Wales\) \(Amendment\) Regulations 2008 No. 713 \(W. 74\)](#)
[The Meat Products \(Scotland\) \(Amendment\) Regulations 2008](#)
[The Meat Products \(Northern Ireland\) \(Amendment\) Regulations 2008](#)

consumer about the true nature of the food or would not enable the food to be distinguished from products with which it could be confused (regulation 8 of the FLR).

5.17 In summary, industry will need to decide if, under general labelling rules, not to declare added starch and/or protein in meat products would mislead the consumer about the true nature of the product on a case-by-case basis.

5.18 Industry will want to take appropriate steps to minimise the possibility that consumers could be misled. For instance, if the addition of starch and/or protein could be considered to be bulking out the meat, as a meat replacement, etc., or if there is any doubt as to whether added starch and protein should be in the name of the food, we recommend that full information about these added ingredients be given prominently in the name of the food for consumer information (see also paras. 5.10-5.11 and 5.24).

It was also emphasized that the presence of protein from a different species must continue to be disclosed in the name of the food e.g. “chicken breast with beef protein”.

Genetically Modified Organisms

Activity in this sphere continued at European level and the following outlines its nature. Interested readers may wish to use commonly available internet search engines to access the individual legal instruments or in case of difficulty contact the author.

Council Decisions COM (2007) 586 and 589 of 09.10.07 instructed Austria to terminate its prohibition on importing and processing two genetically modified maize lines (MON810 and T25). Austria had sought to apply a domestic safeguard clause prohibiting these EU authorised lines, principally on environmental grounds although EFSA had previously ruled that there were

no safety or environmental risks. In respect of three further GM foods, however, despite favourable assessments by EFSA, Member States in the SCoFCAH⁷⁰ were not able to come to a clear majority vote. The foods are:

- ‘Amylopectin starch potato’ EH92-527-1 (BFS-25271-9), producing a potato starch with altered properties as it consists of amylopectin with little or no amylase;
- Maize MON863xNK603 expressing proteins conferring protection both against attack by certain beetles and glyphosate tolerance; and
- Maize MON863xMON810 expressing proteins conferring protection against attack by Coleoptera and Lepidoptera pests.

Accordingly the Commission made proposals for decisions in their favour to the Council of Ministers which acts by a qualified majority and will inform the Parliament. All three GMOs have a kanamycin resistance marker. Validated event specific PCR-DNA methods and reference materials are available from the CRL⁷¹ (JRC) and IRMM⁷² respectively. Similar Council proposals were made for genetically modified maize GA21 (MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 and genetically modified Roundup Ready maize line GA21.

EFSA also considered LLRice 62, a glufosinate-tolerant genetically modified oilseed rape T45, for food and feed uses, import and processing and for renewal of the authorisation of oilseed rape T45 as existing product, under Regulation (EC) No 1829/2003 concluding that they are as safe as their non-GM counterpart for the intended uses.

The Rice Products from the United States of America (Restriction on First Placing on the Market) Regulations 2008⁷³ were made which require a statement with any “rice product” that it only contains rice, from the 2007 or a subsequent harvest, that was subject to the plan of the USA Rice Federation

⁷⁰ Standing Committee on the Food Chain and Animal Health

⁷¹ [Community Reference Laboratory for GM Food and Feed](#)

⁷² [EUROPA - JRC - Institute for Reference Materials and Measurements](#)

⁷³ http://www.opsi.gov.uk/si/si2008/pdf/uksi_20080622_en.pdf with territorial equivalents

aiming to remove “LL Rice 601” from the US export channels. Required also is the original of an analytical report issued by a laboratory referred to in Annex II to the Commission Decision confirming that the product does not contain the genetically modified rice “LL RICE 601”.

The Food Standards Agency has issued a Guidance note for sampling food and feed to determine the presence of genetically modified (GM) material⁷⁴. This is intended to provide detailed guidance to officers responsible for the sampling of food and feed for the presence of GM material.

Puffer Fish

Lastly, as a reminder that misdescription can sometimes be deadly, a warning was issued during 2007 by the US Food and Drug Administration (FDA) about consumers not buying or eating imported fish incorrectly labelled as monkfish, which actually may be puffer fish, containing a potentially deadly toxin called tetrodotoxin. Eating puffer fish that contain this potent toxin can result in serious illness or death.

HEALTH & NUTRITION

The emerging consensus of the national importance of the crucial links between nutrition and health is reflected in the nature and extent of new legislation being developed on nutrition topics.

After extensive consultation, in May, the FSA board took the decision for the mandatory fortification of bread or flour with folic acid. In June, the FSA Board discussed the practicalities of implementing mandatory fortification and

⁷⁴ [Food Standards Agency - Sampling food and feed for genetically modified \(GM\) material guidance](#)

controlling the voluntary addition of folic acid to products, such as breakfast cereals and spreads, to prevent over-consumption by some groups.

The Infant Formula and Follow-on Formula Regulations were made in Northern Ireland and in Wales in December 2007 giving effect to Commission Directive 2006/141/EC putting in place detailed rules for these products.

ADDITION OF VITAMINS AND MINERALS TO FOOD

This sector encompasses diverse aspects of the food industry and was regulated if at all in different ways across Member States, resulting in sub-optimal protection of consumers and barriers to trade. The first piece of specific EU wide legislation to deal with the voluntary addition of vitamins and minerals to food, Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (AVM)⁷⁵, came into force on 1 July 2007 and was directly applicable to all Member States. The FSA began consultation on draft domestic regulations⁷⁶ and draft guidance for food business operators in March 2007⁷⁷. Some Member States apply national rules on the mandatory addition of nutrients to certain foods (e.g. for margarine and flour in the UK). In addition, there are Community rules requiring the mandatory addition of nutrients to a number of foods for particular nutritional uses (PARNUTS foods). AVM is only concerned with the voluntary addition of vitamins and minerals to foods other than food supplements (separately regulated by Directive 2002/46/EC). Key provisions of AVM are:

- It defines the purposes for which additions are allowed;

⁷⁵ [European Regulation 1925/2006](#)

⁷⁶ Putting into place offences, penalties and enforcement provisions so that the regulation can be enforced. Separate regulations required for each UK home territory.

⁷⁷ [Food Standards Agency - Addition of vitamins and minerals and certain other substances to foods \(England and Wales\)](#)

- It lists vitamins and minerals, and the substances from which they may be derived (e.g. L-ascorbic acid for vitamin C or ferric ammonium citrate for iron), permitted to be added to foods – the ‘positive lists’;
- It sets criteria for establishing maximum levels of addition (none were set initially) and provides for the setting of minimum levels;
- It prohibits the addition of vitamins and minerals to fresh produce and alcoholic drinks;
- It lays down specific labelling requirements, including compulsory nutrition labelling; and
- It will not affect national rules on mandatory fortification, although it does not exclude the possibility of future harmonisation of mandatory rules.

The Regulation recognises that vitamins and minerals, in a bioavailable form, may be added to foods, whether or not they are usually contained in that food, to take into account a clinical or sub-clinical demonstrated deficiency. It recognises improved nutrition of the population or in specific groups or to take into account potential deficiencies. There is also acknowledgement of evolving science on the role of vitamins and minerals in nutrition and consequent effects on health. And it introduces powers to take action at Community level to restrict other substances that may be added to food where there are safety concerns over such additions⁷⁸.

By the end of 2007 many Member States (MS) had yet to agree their positions on the controversial subject of setting minimum and maximum levels of vitamins and minerals in foodstuffs, including food supplements. EFSA had established upper levels for 16 vitamins and minerals although for some it was not possible to establish upper levels as there was either insufficient scientific data or where studies had been undertaken, there was no evidence

⁷⁸ Examples of such substances that national authorities have controlled include Kava-kava, aristolochic acid, and ingredients of some stimulant drinks.

of toxicity at the highest level tested. The Commission⁷⁹ had listed Safe Upper Levels (SULs) and Guidance Levels (GLs) set by other scientific bodies (including the UK's Expert Group on Vitamins and Minerals, EVM⁸⁰) where EFSA/SCF had not set levels and asked MS to consider which level should be used as the upper level for total intake of these nutrients. The Commission held the view that it was not proportionate to set maximum amounts where there was no indication of adverse effects and suggested that setting of maximum levels could be waived for vitamin B1, B2, B12, biotin, pantothenic acid, chromium III and vitamin K. Some MS advocated the setting of maximum levels for all vitamins and minerals. The UK supported the approach proposed by the Commission. The Commission also suggested that there would be an agreement for a 15% of RDA minimum level for vitamins and minerals in foodstuffs (fortified food and supplements) unless any evidence is submitted to support another level. The issue of tolerance levels for the stated content on labels is being discussed under the revision of the nutrition labeling directive.

AVM was amended in January 2008 by Regulation (EC) No 108/2008^{81,82} to allow the Commission to establish additional foods to which particular vitamins or minerals may *not* be added and to take decisions to establish and/or amend the lists of authorised, prohibited or restricted other substances. The Commission is also empowered to define such things as purity criteria, maximum amounts, minimum amounts and other restrictions or prohibitions on the addition of vitamins and minerals to food. Lastly the ability to establish derogations from certain provisions of the regulation was established.

The Commission raised the issue of sodium chloride and concluded that this legislation is not the best place to limit salt intake.

⁷⁹ Orientation paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs; Document prepared by Directorate-General Health and Consumer Protection
July 2007

⁸⁰ [Food Standards Agency - Final report of the EVM](#)

⁸¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:039:0011:0013:EN:PDF>

⁸² [SCADPlus: The addition of vitamins and minerals to foods](#)

Finally, as part of its continuing evaluation EFSA also gave a scientific opinion on vanadium compounds for inclusion in PARNUTS foods and supplements and in March concluded that the use of mixed tocopherols and tocotrienol tocopherol as a source of vitamin E in food supplements for the general population at the proposed levels of use is not of safety concern. However, the available safety data were insufficient to conclude on the safety of the proposed use and use levels of all-tocotrienol vitamin E preparations.

FOOD SUPPLEMENTS

The consequences of the Food Supplements (England) Regulations 2003 implementing Directive 2002/46/EC, with devolved equivalents, moved further in the latter quarter of 2007. Of the 500 or so dossiers received by EFSA in 2005 for a scientific opinion on nutrients added to food supplements and foods currently on the market, some 200 were sufficiently detailed. However some 300, all from the UK, were basic one page submissions, insufficiently detailed for an opinion on safety and bioavailability. The FSA made companies aware of the deficit in information in 2005 and EFSA informed the Commission in September 2007 that if additional data was not forthcoming by the end of 2007 no assessments could be made. Where dossiers were lodged before 12 July 2005 products can continue on sale until 31 December 2009. EFSA and FSA have made companies aware of the situation.

FSA sought stakeholders' views on the EFSA opinions and the anticipated proposal for amendments to the Annexes of the Directive to add calcium malate, magnesium malate, zinc malate, and magnesium potassium citrate to the lists of permitted vitamin and mineral substances.

HEALTH & NUTRITION CLAIMS

Regulation (EC) No 1924/2006⁸³, intended to protect consumers from false or misleading claims and to provide uniform regulation across Europe was dealt with extensively in the previous report in this series⁸⁴. After consultation by the FSA⁸⁵ the regulation became the subject of domestic UK legislation in October 2007⁸⁶ with a list of UK health claims^{87,88} submitted to FSA for screening before appraisal by EFSA.

There was no list of approved health claims in force on 1 July 2007, the date of application of Regulation 1924/2006. For this reason, the Regulation provides for transitional measures for health claims other than those referring to the reduction of disease risk and to children's development and health. For disease reduction claims no transitional measure was needed because of the prohibition of claims referring to the prevention, treatment or cure of a disease by Directive 2000/13/EC. Thus products carrying such claims should not have been on the Community market. The category of claims referring to children's development and health was introduced at a very late stage of the procedure for the adoption of Regulation (EC) No 1924/2006, without providing for transitional measures. However, products carrying such claims are already present on the Community market. In order to avoid disruption of the market, it was therefore agreed by the Commission to submit claims referring to children's development and health to the same transitional measures as the other health claims. This was put into effect by Regulation (EC) No 109/2008⁸⁹ of 15 January 2008 amending Regulation (EC) No 1924/2006.

⁸³ http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_012/l_01220070118en00030018.pdf

⁸⁴ [Walker, M. Government Chemist - Home - Publications - Foresight Reports](#)

⁸⁵ [Food Standards Agency - Nutrition and health claims made on foods \(England and Wales\)](#)

⁸⁶ [The Nutrition and Health Claims \(England\) Regulations 2007 No. 2080](#) with territorial equivalents as follows

[The Nutrition and Health Claims \(Scotland\) Regulations 2007 No. 383](#)

[The Nutrition and Health Claims \(Wales\) Regulations 2007 No. 2611 \(W. 222\)](#)

[The Nutrition and Health Claims Regulations \(Northern Ireland\) 2007 No. 349](#)

⁸⁷ [Food Standards Agency - UK list of health claims](#)

⁸⁸ http://www.sacn.gov.uk/pdfs/sacn_08_04.pdf

⁸⁹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:039:0014:0015:EN:PDF>

Much preliminary work was also done during the year to establish the basis for nutrient profiles, an issue that remains controversial. The concept was introduced to avoid a situation where claims might mislead consumers trying to make healthy choices as to the overall nutritional quality of a food product in the context of a balanced diet.

EFSA initially recommended that the choice of nutrients to be included in nutrient profiles should be driven by their public health importance for EU populations⁹⁰. These nutrients include saturated fatty acids, sodium, dietary fibre and unsaturated fatty acids, intakes of which generally do not comply with nutrient intake recommendations in many Member States. Unsaturated fatty acids might not be needed if saturated fatty acids are included. The use of dietary fibre might be limited to certain food groups that are important dietary fibre sources and for which the use of dietary fibre to discriminate between food products would be most relevant, e.g. cereal products. Trans fatty acids might be included for some food groups but are of decreasing public health importance as intakes in the EU have declined considerably. Total sugar content might be included for particular food groups, e.g. beverages, and foods, such as confectionery products, that might be consumed with a high frequency. Depending on the scheme adopted, energy density or total fat, as well as other nutrients, might also be considered. However, the total number of nutrients included would have to be limited to avoid overly complex nutrient profiles. The Panel recognises the scientific limitations intrinsic in the use of nutrient profiles to classify foods as eligible to bear claims and the need for expert judgement to be applied. There is an inherent difficulty in seeking to apply to individual food products nutrient intake recommendations that are established for the overall diet. Furthermore, the potential of food products (as purchased) to adversely affect the overall dietary balance does not take into account changes in nutrient content that occur during cooking or preparation, such as addition of fat, sugar or salt, nor does it take into account the habitual intake of the food or the pattern of

consumption. In addition, the lack of uniform data for food composition and food consumption across the EU, as well as differences in nutrient intake recommendations and food based dietary guidelines between Member States, makes it more difficult to set nutrient profiles at EU level than at national level. The basis for expert judgements needed to address such limitations should be transparent in order to avoid variable outcomes.

EFSA subsequently published an opinion⁹¹ and will continue to assist the European Commission in establishing a nutrient profile scheme, by developing a suitable food composition database and providing advice on its use in testing any proposed system.

By Regulation (EC) No 107/2008⁹² of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods the Commission adopted Community measures concerning the labelling, presentation and advertising of certain foods; to establish derogations from certain provisions of Regulation (EC) No 1924/2006; to establish and update nutrient profiles and the conditions and exemptions under which they can be used; to establish and/or amend lists of nutrition and health claims and to amend the list of foods in respect of which the making of claims is restricted or prohibited.

NOVEL FOODS

Commission Decision 2008/36/EC of 10 January 2008⁹³ authorised the placing on the market of rice drinks with added phytosterols/phytosteranols as novel food under Regulation (EC) No 258/97. In 2004 a Finnish company

⁹⁰ [EFSA: Nutrient profiles: EFSA consults experts and assesses options](#)

⁹¹ [EFSA: The setting of nutrient profiles for foods bearing nutrition and health claims pursuant to Article 4 of the Regulation \(EC\) No 1924/2006 - Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies](#)

⁹² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:039:0008:0010:EN:PDF>

⁹³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:008:0015:0017:EN:PDF>

made a request to the competent authorities of Finland to place rice drinks with added phytosterols on the market. The Finnish assessment was favourable but there were objections from other MS and the Commission referred it to EFSA which came to the conclusion that there is no reason to believe that the product would increase the risk of over-consumption of phytosterols. Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters ensures that consumers receive the information necessary in order to avoid excessive intake of additional phytosterols. The product has been passed for sale with the proviso that it shall be presented in such a manner that it can be easily divided into portions that contain a maximum of 3 g of added phytosterols/phytostanols. An EFSA report on Consumption of Food and Beverages with Added Plant Sterols highlights that while there seems to be little over-consumption of such products in the EU, a small established subgroup appears to be consuming in excess of recommended amounts. It also reveals low consumer awareness of labelling and dietary guidelines for such products and of the need to consume sufficient fruit and vegetables to ensure robust blood carotenoid levels.

NUTRITION LABELLING

Nutrition labelling was in part overtaken by the major review of labelling which will take the form of a Regulation on Food Information (see above under the heading Labelling) that will be subject to Co-Decision procedures i.e. it will require the approval of both Council of Ministers and the European Parliament (EP). In addition in March 2008 FSA consulted⁹⁴ on the European Commission's proposal to amend the Nutrition Labelling Directive (90/496/EEC). The key proposals are a definition of dietary fibre, new energy conversion factors for fibre and erythritol and updating Recommended Daily Allowances (RDAs) for vitamins and minerals.

⁹⁴ [Food Standards Agency - Nutrition labelling of foodstuffs \(Northern Ireland\)](#)

PARNUTS - FOOD FOR PARTICULAR NUTRITIONAL USES

Following FSA⁹⁵ consultation PARNUTS regulations were made⁹⁶ (The Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2007 No 2591) with territorial equivalents to:

- amend the Infant Formula and Follow-on Formula Regulations 1995 to permit cows' milk whey protein hydrolysates;
- amend the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 to remove the prohibition on labelling etc that refers to a reduction in the sense of hunger or increase in satiety, and make further amendments to a range of other measures.

Scotland and Northern Ireland benefited from similar PARNUTS amendment Regulations.

Council Directive 89/398/EEC of 3 May 1989 on foodstuffs intended for particular nutritional uses has been substantially amended several times and because further amendments are to be made, it was decided to recast the Directive in the interests of clarity as a proposal⁹⁷. There has also been some discussion about the desirability of special provisions for foods for persons suffering from carbohydrate-metabolism disorders (diabetes) in this same directive.

REGULATION

OFFICIAL FEED & FOOD CONTROLS

⁹⁵ <http://www.food.gov.uk/consultations/consulteng/2007/parnutsenconsult07>

⁹⁶ http://www.opsi.gov.uk/si/si2007/pdf/uksi_20072591_en.pdf

⁹⁷ [EUR-Lex - 52008PC0003 - EN](#)

The year opened in April with an FSA consultation on the draft Official Feed and Food Controls (England) Regulations 2007⁹⁸ to implement in the UK further provisions of Regulation 882/2004. The reasons for introducing the new Statutory Instrument (SI) are to:

- give effect to EU requirements for the competent (regulatory) authorities to (a) charge businesses for expenses arising from 'additional official controls', and (b) recover certain administration costs associated with assistance and co-operation between the Member States and the Commission;
- update the definitions required for interpretation of the SI to reflect changes/expected changes to Community and national legislation, and update the areas of responsibilities designated to the competent authorities;
- update the legal powers of the authorities responsible for controls of feed/food of non-animal origin from outside the EU to help ensure more effective enforcement; and
- establish an offence of introduction into the UK countries prohibited food or feed.

The Official Feed and Food Controls (England) Regulations 2007⁹⁹ came into force in December 2007 and revoke and re-enact with changes the 2006 Regulations. Devolved equivalents apply¹⁰⁰. This brings up to date the various corrigenda to the original official controls Regulation 882/2004.

NATIONAL CONTROL PLAN

⁹⁸ [Food Standards Agency - Draft Official Feed and Food Controls \(England\) Regulations 2007](#)

⁹⁹ [The Official Feed and Food Controls \(England\) Regulations 2007 No. 3185](#)

¹⁰⁰ [The Official Feed and Food Controls \(Scotland\) Regulations 2007 No. 522](#)
[The Official Feed and Food Controls \(Wales\) Regulations 2007 No. 3294 \(W. 290\)](#)
[The Official Controls \(Animals, Feed and Food\) Regulations \(Northern Ireland\) 2007 No. 133](#)

The Food Standards Agency and the four UK Agriculture/Rural Affairs Departments reviewed the UK's National Control Plan, under Regulation 882/2004 on official controls, for the period January 2007 to March 2011. A revised version was published in February 2008¹⁰¹. The Plan's purpose is to ensure that effective control systems are in place for monitoring and enforcing feed and food law, animal health and animal welfare rules, and plant health law. Regulation 882/2004 requires that plans be kept under review and revised regularly. The first review of the UK Plan has thus been completed. No significant changes have been made as a result. However, revisions reflect organisational and legislative changes. The document gives readers a key understanding of the policy and mechanisms of food and feed regulation in the UK.

EFSA – EUROPEAN FOOD SAFETY AUTHORITY

Further details of these and other developments are available on the EFSA website¹⁰².

In September, EFSA discussed a revised policy on declarations of interest further to bolster its mechanisms to safeguard the independence of its scientific work. It also created a new panel to take on some of the tasks of the AFC panel on food additives and food contact materials in order to achieve greater scientific output in these areas.

EFSA view as useful the introduction of a 'Qualified Presumption of Safety' approach for the assessment of the 100 or so species of micro-organisms likely to be referred for market authorisation as sources of food or feed additives, enzymes or plant protection products. The QPS approach is based

¹⁰¹ [Food Standards Agency - National Control Plan for the United Kingdom](#)

on four aspects: establishing identity to a taxonomic group, body of knowledge, possible pathogenicity and end use.

EFSA has also called for reference materials and further work on the analytical methods for the protozoan parasite *Toxoplasma gondii*, in order better to monitor its occurrence in food, animals and humans.

EFSA launched a public consultation on its draft scientific opinion on the implications of cloning cattle and pigs on food safety, animal health and welfare and the environment. Although death and disease rates of clones are significantly higher than those observed in conventionally reproduced animals, the fact that a proportion of clones and their offspring are healthy indicates that somatic cell nuclear transfer (SCNT) can be successfully used as a reproductive technique in cattle and pigs. Healthy clones and healthy offspring do not pose food safety risks and the proportion of unhealthy clones is likely to decrease as the technology improves.

Food products obtained from healthy cattle and pig clones and their offspring, i.e. meat and milk, are within the normal range with respect to the composition and nutritional value of similar products obtained from conventionally bred animals. In view of these findings, and assuming that unhealthy clones are removed from entering the food chain as is the case with conventionally bred animals, it is very unlikely that any difference exists in terms of food safety between food products originating from clones and their progeny compared with those derived from conventionally bred animals. No environmental impact is foreseen as a result of animal cloning, but there is only limited data available. At present cloning is not a commercial practice in Europe and there is no specific authorisation procedure for food products from cloned animals in the EU.

¹⁰² [EFSA: Home](#)

The European Commission has requested an initial scientific opinion from EFSA relating to the risks arising from nanoscience and nanotechnologies on food and feed safety and the environment. The request also asks to identify the nature of the possible hazards associated with actual and foreseen applications in the food and feed area and to provide general guidance on data needed for the risk assessment of such technologies and applications.

In February 2008 EFSA published its annual management plan for 2008. Its priorities are to continue to provide risk managers in the European Institutions and EU Member States with scientific advice on existing and emerging risks. The Authority will remain committed to the core standards of scientific excellence, openness, transparency, independence and responsiveness. It will streamline its procedures and adapt its working practices to meet its target outputs of scientific opinions and statements to the highest quality standards and increase its presence and visibility in the Member States. In addition, the positioning of EFSA in the international food safety environment is important in order to develop recognition for its work with the international risk assessment community. Likely new challenges for 2008 will include nanoparticles in food, animal cloning and the application of QPS (qualified presumption of safety) in microbiological risk assessment. More than two-thirds of EFSA's budget of €66.4m will be used to provide scientific opinions and advice and enhance risk assessment methodologies. Communication will continue to be a critical function of the Authority.

LOCAL AUTHORITY AUDIT

In September 2007 the FSA issued proposals to update the current Code of Practice on Food Law Enforcement by Local Authorities. Taking account of the Hampton review the proposed changes aim to move from current

inspection focused policy to a suite of interventions to drive up levels of compliance and a risk based inspection regime.

The key changes for audits are:

- to take more account of, and to build upon, local authorities' own audit activity of their feed and food law enforcement services, where these local audit arrangements can be verified as sufficiently robust to meet European Union (EU) audit criteria;
- to be more risk-based in their approach and in the selection of local authorities;
- to have a greater focus on local authorities' feed and food law enforcement service outcomes.

The proposals take into account the wider government agenda on the performance management framework for the public sector, and EU requirements on Competent Authorities relating to the audit of Official Controls of feed and food law.

SUSTAINABLE DEVELOPMENT

In March FSA began consultation on the Agency approach to sustainable development in policy making.

DISPUTE RESOLUTION

The EU made comments on the Codex Circular 2006/47-MAS, Draft Guidelines for Settling Disputes over Analytical (Test) Results. EU preference is for the definition of a dispute to be when the difference between results

obtained in two laboratories is larger than the sum of their two method uncertainties (rather than the Codex approach using reproducibility limits). Further refinement based on a geometric rather than arithmetic approach was also preferred.

HIGH RISK NON-POAO (PRODUCTS OF NON-ANIMAL ORIGIN)

Throughout the year FSA issued updates to its consultation¹⁰³ on EU discussions on official controls implementing rules under 882/2004 for import controls for 'high risk' feed and food of non-animal origin (non-POAO). The issues were mainly of an administrative nature and included a discussion on time limits for detention of consignments. Some MS argued for a 15 day limit as in the case under Decision 504/2006 on aflatoxins. The UK argued that controls are already required, under 882/2004, to be efficiently and effectively carried out and this is sufficient. Proposed criteria for inclusion in such a list include RASFF notifications, FVO reports, known quantities of imports, reports from third countries, inter-MS communications and EFSA and other scientific assessments. Further discussion in December led to a draft Commission regulation including the above criteria along with delisting criteria. It is intended that designated points of first entry and points of import (DPFA/DPI) should be notified to the Commission, with random sampling for analysis at the latter. Fees and charges may be collected from the feed/food business operators to cover the costs of official control but the Commission has not laid down any minima and may adopt the Regulation without agreeing fee levels. The proposed regulation includes a draft high risk list consisting of analyses for aflatoxins, Cd, Pb, ochratoxin A, Sudan dyes and OP pesticides residues from designated third countries. Frequencies of checks are also given. FSA believes the system will be unworkable without agreed fees, which should be set, for now, at the level of costs for carrying out the controls. FSA also has concerns about requirements that should be set by MS for approval of DPFAs

¹⁰³ [Food Standards Agency - Import controls for 'high-risk' feed and food of non-animal origin](#)

and DPIs. At the time of writing (July 2008) discussions continues at EU level on this topic.

Lastly, an EU Green Paper on bio-preparedness was published in September 2007 with the objectives of stimulating a debate and a process of consultation at European level on the reduction of biological risks and enhancing preparedness and response to potential terrorist attack with biological material. While the risk of a bioterrorist attack is statistically low its consequences on the food supply chain could be devastating. The introduction of pathogens or a disease outbreak would have considerable social and economic consequences.

FEEDING STUFFS & FERTILISERS

During the year the Feed (Specified Undesirable Substances) (England) Regulations 2007¹⁰⁴ were made, further amending the 2005 Regulations in relation to the organochlorine compounds aldrin and dieldrin (new limits) per Directive 2006/77/EC.

The Feed (Corn Gluten Feed and Brewers Grains) (Emergency Control) (England) (Revocation) Regulations 2007 revoke the 2005 Regulations requiring importers to provide a certificate of analysis of freedom from Bt10 GM Maize, a non EU authorised line.

Commission Directive 2008/4/EC of 9 January 2008 amending Directive 94/39/EC as regards feedingstuffs intended for the reduction of the risk of milk fever allowed zeolite (synthetic sodium aluminium silicate) to be added to feedingstuffs for dairy cows and required the different sources of calcium to be indicated on the label together with their quantity along with a recommendation to seek nutritional advice. The Feeding Stuffs (England)

(Amendment) Regulations 2008¹⁰⁵ transpose this into law in the UK. Directive 2008/4 was amended by a Corrigendum that corrected the implementation deadline from 24 June to 30 July 2008.

FSA consultation occurred in January 2008¹⁰⁶ on the proposed feed law enforcement practice guidance in Great Britain. This covers qualifications and training for sampling, hazards, alerts, RASFF, liaison with other MS etc.

Commission Regulation (EC) No 121/2008 of 11 February 2008¹⁰⁷ prescribed the method of analysis for the determination of starch content in preparations of a kind used in animal feeding (CN code 2309). A list of matrices is given. The samples are homogenised by milling. The sample is washed with 40 % ethanol to eliminate soluble sugars and soluble products of starch decomposition. Enzymolysis to glucose is achieved by successive treatment with thermostable alpha-amylase at 100 °C and amyloglucosidase at 60 °C. The glucose is determined by HPLC after clarification of the solution.

There was a Proposal for a Regulation on the placing on the market and use of feed. The project is included in the Commission's rolling programme of simplification. The proposal includes tolerances for the compositional labelling of feed materials. Meanwhile, Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes (Codified version) was published.

EFSA gave scientific opinions on the feed additives narasin and lasalocid. Narasin can be found in eggs when given to laying hens and EFSA considered non intentional cross contamination of the feed of non-target species of up to 10 %. For narasin, human exposure to the non-target

¹⁰⁴ [The Feed \(Specified Undesirable Substances\) \(England\) Regulations 2007 No. 3008](#)

¹⁰⁵ [The Feeding Stuffs \(England\) \(Amendment\) Regulations 2008 No. 1523](#)

¹⁰⁶ [Food Standards Agency - Proposed feed law enforcement practice guidance in Great Britain \(England\)](#)

¹⁰⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:037:0003:0008:EN:PDF>

species products would be well below the ADI of 5 µg/kg bodyweight. Similar considerations showed that the same ADI for lasalocid could be slightly exceeded but this was considered a rare event.

EFSA also considered the safety and efficacy of Danisco Xylanasa G/L as a feed additive and found that there was no genotoxic hazard nor a toxic response other than possible eye irritation and the respiratory sensitisation expected of a proteinaceous substance. EFSA gave a scientific opinion on chlordane as an undesirable substance in animal feed. A scientific opinion of EFSA's Panel on Contaminants in the Food Chain considered glucosinolates as undesirable substances in animal feed. All measured concentrations in animal-derived products are much lower than those found in vegetables for human consumption, and are unlikely to induce adverse health effects in consumers. Cross-contamination of non-target feedingstuffs by a number of authorised feed additives was considered by EFSA. Although data were limited, there was no indication of appreciable risk to consumers from ingestion of residues in products from animals exposed to feed cross contamination up to 10 % of the maximum permitted concentrations for the additives semduramicin, maduramicin, salinomycin and monensin.

Commission Regulation (EC) No 61/2008 of 24 January 2008 amending Annex II to Council Regulation (EEC) No 2377/90 permitted the veterinary medicinal product dinoprostone in foodstuffs of animal origin without a MRL owing to its structural similarity to, and the fact that dinoprostone is rapidly metabolised to, the already permitted dinoprost tromethamine.

Feed additives authorisations were made as follows:

Commission Regulation	Additive
1137/2007 of 01.10.07	<i>Bacillus subtilis</i> (035) 4b1821 spore concentrate

	as a zootechnical additive for gut flora stabilisation in chickens. A microbiological method for enumeration is given.
1138/2007 of 01.10.07	New use of benzoic acid
1139/2007 of 01.10.07	Authorisation of L-arginine
1140/2007 of 01.10.07	New use of beta-glucanases, alpha-amylase and bacillolysin for chickens.
1141/2007 of 01.10.07	Authorisation of 3-phytase
1380/2007 corrected on 28.11.07	Authorisation of endo-1,4-beta-xylanase
1500/2007 of 18.12.07	New use of 6-phytase (Ronozyme)
1501/2007 of 18.12.07	New use of endo-1,4-beta-xylanase
1520/2007 of 19.12.07	Permanent authorisation of E1616 endo-1,4-beta-glucanase E1715 <i>Lactobacillus acidophilis</i> E1707 <i>Enterococcus faecium</i> E1710 <i>Saccharomyces cerevisiae</i>
1521/2007 of 19.12.07	New use of <i>Enterococcus faecium</i>

CONCLUSION

This research provides a key strand of evidence about future demands on the Government Chemist statutory function. It will be used to inform project prioritisation and resourcing decisions, as well as the future formulation of GC capability building projects. Emerging themes and priorities will also be communicated to stakeholders through knowledge transfer activities, and will provide context for more specific advice.

We recommend that this research be continued as a supporting pillar of the new Government Chemist programme (2008-11). In future, we will aim to summarise key findings on a quarterly basis so that the GC and stakeholders can utilise the knowledge in a timely and effective manner.