Food and Feed Law

Review of Changes in Food and Feed Legislation affecting the UK

July 2011 – September 2011

Statutory Analysis

Government Chemist Programme

LGC/R/2011/197

research • measurement • science • expertise • quality • safety •

LGC *Setting standards in analytical science*

Report:

European and UK Regulation of Food and Feed

Quarterly Review
July 2011 – September 2011

Statutory Analysis
Government Chemist
Programme

Contact Point: M Walker

michael.walker@lgcgroup.com

Prepared by:
Michael Walker and
Chris Torrero

LGC/R/2011/197

January 2012

Contents

Legislation Summary 1
Introduction 3
Acknowledgements 4
Cross-Cutting Issues 4
Radionuclide levels in food products from Japan 4
Horizon Scanning 4
Data collection for the identification of emerging risks 4
EFSA Emerging Risks Exchange Network 5
EFSA Stakeholder Consultative Group on Emerging Risks 5
The Foresight Programme 5
Medical Information System (MedISys) 5
Food Safety 6
Regulated Contaminants in Food 6
Mycotoxins 6
Aflatoxin 6
Ochratoxin 6
Zearalenone 6
Other regulated contaminants 6
Arsenic 6
Cadmium and Lead 7
Dioxins, furans and PCBs 7
Inorganic tin 8
3-MCPD 8
Mercury 9
Methods of sampling and analysis for contaminants 9
Polycyclic aromatic hydrocarbons 9
Other Contaminants 10
Acrylamide 10
Polybrominated diphenyl ethers (PBDEs) in food 10
Food Allergens 10
Risk factors for food allergy 10
Food Additives 10
Aluminium in Food 10
Ban of whitening agents for flour in China 10
Calcium lignosulphonate 11
Calcium Carbonate 11
Caramel Colouring 11
Enzymes 11
Lycopene 11
Phthalates 12
Sunset Yellow (E 110) 12
Food Contact Materials 12
Evaluation of recycling processes 12
Hexabromocyclododecanes (HBCDDs)- flame retardants 13
Migration of mineral oils from recycled newspapers 13
Non-Plastic Food Contact Materials 13
Extraction Solvents in Food 14
Natural Mineral and other Bottled Waters 14
Pesticides 14
Veterinary Residues 15
Residue Monitoring Results 2009 16
Nanomaterials 16
Toxicology 16
Genotoxicity 16
Kava 16

Transmissible Spongiform Encephalopathys, TSE/BSE 17
Food Hygiene 18
Antimicrobial Resistance 18
Campylobacter in broiler meat production 18
EU Trends 18
Foodbourne Virus 19
Lactic Acid Treatment 19
Risk Characterisation 20
Salmonella 20
Shiga toxin/verotoxin-producing *Escherichia coli* (STEC/VTEC) 21
Consumer Choice and Prevention of Fraud 22
Animal Welfare 22
Composition and Labelling 22
Fruit Juices and Fruit Nectars 22
Fruit juice authenticity 22
Organic Food 22
Fish parasites 22
Food Irradiation 23
GMOs 23
Novel Foods 24
Health and Nutrition 25
Health Claims 25
Red yeast rice – monacolins 27
Food Supplements 27
Glavonoid 27
Regulation 28
Official controls - products of non- animal origin 28
Official controls - products of animal origin 28
EFSA 29
EFSA Annual Report 29
Electronic transmission of results of analytical measurement 29
EU Almanac 29
FSA 29
The Food and Drug Administration 30
Feeding Stuffs and Fertilisers 30
Undesirable Substances in Feed 30
Nitrite, Melamine, *Ambrosia* spp., Coccidiostats and Histomonostats 30
Catalogue of feed materials 30
Feed Additives 30

Legislation Summary

Radionuclide levels in food products from Japan

Following the accident at the Fukushima nuclear power station on 11 March 2011, a Commission Implementing Regulation imposing special conditions governing the import of feed and food originating in or consigned from Japan was adopted on 25 March 2011. In September 2011 this was renewed and monthly reviews retained.

Ochratoxin A in wheat and wheat flour from Canada

In certain circumstances sampling and analysis by a third country can replace controls exercised in the UK. In 2007 Canada submitted an application to the Commission for approval of pre-export checks performed by the Canadian Grain Commission for ochratoxin A contamination in wheat and wheat flour intended for export to the EU. This has been assessed and approved. In consequence Member States can reduce the frequency of sampling and analysis on those commodities provided each consignment is accompanied by a report containing the results of sampling and analysis and provided other administrative details have been met.

PAH, dioxins, furans and PCBs

The current use of benzo(a)pyrene as the only marker for polycyclic aromatic hydrocarbons, was overturned by new maxima for the sum of four substances (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene). New action levels have been set for dioxins, furans and PCBs in certain foods.

Methods of sampling and analysis for contaminants

Methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs have been revised.

Novel Foods

Fermented black bean extract and phosphatidylserine from soya phospholipids have been approved as novel food ingredients. Phosphated maize starch was also approved to be placed on the market in the EU as a novel food ingredient for use in baked bakery products, pasta, breakfast cereals and cereal bars to a maximum content of 15 %. The designation of phosphated distarch phosphate authorised by this Decision on the labelling of the foodstuff containing it shall be ‘phosphated maize starch’.

Official controls - products of non- animal origin

Commission Regulation (EC) No 669/2009 (see previous editions of this work) lays down rules concerning the increased level of official controls to be carried out on imports of feed and food of non- animal origin listed in an Annex (Annex I thereto ‘the list’), at the points of entry into the EU. The list was further amended and republished in its entirety. The parameters in question cover aflatoxins, pesticides, Aluminium in Chinese noodles, Cadmium, Lead, ochratoxin and Sudan dyes. Of these there are few analytical problems however the methods appropriate for Aluminium in noodles are under investigation by several bodies including the Government Chemist.

Official controls - products of animal origin

Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption in particular, meat inspections and animal diseases. This was amended in the quarter mainly by reference to animal diseases covered by EU legislation in relation to inspection unless reference is made to currently unknown diseases originating in third countries. The opportunity was also taken to

allow an official veterinarian to impose industrial heat treatment, or other treatment to eliminate salmonella on certain fresh poultry meat.

Additionally, new provisions for extraction solvents in food and for revised MRLs for a range of pesticides were made.

Introduction

This report, covering the period July to September 2011, is the second of a quarterly series in the 2011 to 2014 Government Chemist programme in LGC aimed at providing stakeholders with reviews of recent developments in food and feed law and related scientific and regulatory issues

This report forms part of the project RF1 (Milestone RF1/1) in the programme. It concentrates on legislative changes that relate to chemical measurement and the role of the Government Chemist function and its stakeholders. However it also includes general issues in food and feed to ensure contextual awareness.

This report continues the practice of grouping legislation into six categories. Thus the structure and content of the report are as follows:

1. **Cross-Cutting Issues**
2. **Food Safety**
   including contaminants, TSEs, hygiene, food contact materials and additives;
3. **Consumer Choice and Prevention of Fraud**
   including composition, general labelling, aspects of GM food and food irradiation;
4. **Health and Nutrition**
   including nutrition labelling, nutrients and supplements;
5. **Regulation**
   dealing with regulatory activities and overarching provisions;
6. **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 and Northern Ireland, devolved 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. The publication of annual reports on the scope of legislation relating to the Government Chemist function[1] complements the quarterly reports in the series of reviews of changes in UK food and feed legislation and provides the Government Chemist with a comprehensive reference base for food and feed law and emerging issues.

Please note – legislation in force and made prior to July 2011 will not necessarily be reiterated herein; please refer to previous annual editions of this work on the Government Chemist website. No responsibility can be taken for the use made of any view, information or advice given. 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.

For any specific legislation this document should be read with the actual measure. Readers must always come to their own view on legislation in force, with expert public analyst and/or legal assistance if appropriate.

The sources of information used have been Office of Public Sector Information (OPSI), Food Standards Agency updates, EFSA and the European legislative information database, Eur-Lex. Extensive use has been made of the explanatory notes that accompany each set of domestic regulations.

[1] Francis, J. 2011 Government Chemist Legislation - Annual statement of statutory scope, available at http://www.governmentchemist.org.uk/Generic.aspx?m=77&amid=1126

Acknowledgements

Funding under the BIS National Measurement Office [2] funded Government Chemist Programme 2011-2014 is gratefully acknowledged.

Cross-Cutting Issues

Radionuclide levels in food products from Japan

Special conditions renewed

Following the accident at the Fukushima nuclear power station on 11 March 2011, a Commission Implementing Regulation (EU) No 297/2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan was adopted on 25 March 2011. This was amended by Commission Implementing Regulation (EU) No 506/2011 of 23 May 2011 [3] and in the quarter was further amended by Commission Implementing Regulation (EU) No 657/2011 of 7 July 2011[4] following sampling and analysis in Japan showing that the production of feed and food in certain prefectures was only to a very limited extent affected by the accident. Therefore, the amending Regulation removed those prefectures from the need for testing of feed and food before export to the EU.

In September 2011, the above provisions were extended until 31 December 2011, rather than to 30 September 2011 as initially foreseen and the principle of a monthly review retained. However since Regulation (EU) No 297/2011 has been amended several times in a short period of time it is was replaced by Commission Implementing Regulation (EU) No 961/2011 of 27 September 2011.[5]

Horizon Scanning

Data collection for the identification of emerging risks

The European Food Safety Agency (EFSA) has started to develop an approach to identify emerging risks in the food and feed chain (see below). In September a report[6] presented the results of an investigation performed by the working group on data collection for the identification of emerging risks related to food and feed (DACO WG). The report is a comprehensive overview of sources (including weblinks) and prioritisation criteria. The WG proposed a procedure to identify, assess, rank and prioritize data sources - a two-step process based on the UK Food Standards Agency use of the National Intelligence Model and

[2] The National Measurement Office, http://www.nmo.bis.gov.uk/
[3] Commission Implementing Regulation (EU) No 506/2011 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:136:0052:0055:EN:PDF
[4] COMMISSION IMPLEMENTING REGULATION (EU) No 657/2011 of 7 July 2011 amending Regulation (EU) No 297/2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:180:0039:0042:EN:PDF
[5] Commission Implementing Regulation (EU) No 961/2011 of 27 September 2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station and repealing Regulation (EU) No 297/2011 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:252:0010:0015:EN:PDF
[6] European Food Safety Authority; Data collection for the identification of emerging risks related to food and feed. EFSA Journal 2011; 9(8):EN-185. [52 pp.] doi:10.2903/j.efsa.2011.EN-185. Available at http://www.efsa.europa.eu/en/supporting/pub/185e.htm Accessed 05.01.12

the Dataquest approach[7] which is potentially quantifiable and can therefore also be used for ranking and prioritisation. This procedure consists of i) an initial classification of the identified data sources, followed by a monitoring period of the pre-selected data sources and ii) a consecutive and more detailed quality assessment of the relevant data sources for ranking and prioritization purposes. For this assessment, the WG defined text descriptors and quality parameters (i.e. link with indicators, data type, geographic and period coverage, language, edition, timeliness, accessibility, clarity and comparability). Then, as a pilot study, based on expert knowledge, the WG proposed data sources in the chemical, biological and nutritional areas, including research projects in the food area from the EU framework programme (n=188). These data sources were linked to eleven priority indicators (the EFSA scientific cooperation working group, ESCO indicators) and qualitatively assessed and profiled. These results led to conclusions and recommendations on a strategy for emerging risk identification (ERI). Such a strategy should encompass the selection of priority areas and the identification of appropriate indicators and associated data sources. Prospective studies, for example by running various risk scenarios, may help in defining such priorities. Close collaboration with relevant research projects, experts and stakeholders is a major condition for a successful ERI. The WG considered that monitoring a large number of data sources is inevitable and therefore recommended EFSA utilises software tools to support the collection and processing of this huge amount of information. Specific automated filtering processes may be designed that enable the selection of the most relevant signals for further analysis by experts.

EFSA Emerging Risks Exchange Network

See previous report[9]

EFSA Stakeholder Consultative Group on Emerging Risks

See previous report[9]

The Foresight Programme

The Foresight Programme advises the UK Government and others about how to ensure today's decisions are robust for an uncertain future. This is done by combining the latest scientific and other evidence with futures analysis to help policy makers tackle complex issues. Foresight brings together different Government departments to stimulate and inform the development of strategies, policies and priorities that are more resilient and robust across a range of possible futures. Foresight is headed by the Government Chief Scientific Adviser, Professor Sir John Beddington, who reports directly to the Prime Minister and Cabinet. It is a part of the Government Office for Science within the Department for Business, Innovation & Skills. More information about Foresight and the impact it has made in Government can be found on the Foresight website at www.bis.gov.uk/foresight [8]

Medical Information System (MedISys)

See previous report[9]

[7] Rodgers CJ, Roque A and Marcos López M, 2011. DATAQUEST: Inventory of data sources relevant for the identification of emerging diseases in the European aquaculture population. External Scientific Report submitted to EFSA, NP/EFSA/AMU/2009/02, 109 pp. URL: http://www.efsa.europa.eu/en/scdocs/scdoc/90e.htm.

[8] Foresight Annual Review, 2010, http://www.bis.gov.uk/assets/bispartners/foresight/docs/general-publications/11-p91-foresight-annual-review-2010 Accessed 06.01.12

[9] Michael Walker and Chris Torrero, 2011, Food and Feed Law: Review of Changes in Food and Feed Legislation affecting the UK April 2011 – June 2011, Available at http://www.governmentchemist.org.uk/Generic.aspx?m=77&amid=1224

Food Safety

Regulated Contaminants in Food

Mycotoxins

Aflatoxin

No further developments this quarter

Ochratoxin

In certain circumstances sampling and analysis by a third country can replace controls exercised in the UK. Regulation (EC) No 1881/2006 sets maximum levels for certain contaminants in foodstuffs including permitted maximum concentrations of ochratoxin A in foodstuffs. Regulation (EC) No 882/2004 obliges Member States to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency in order to achieve the objectives of the Regulation, which are *inter alia* preventing, eliminating or reducing to acceptable levels risks to humans and animals. Article 23 of the Regulation provides for approval of specific pre-export checks that a third country carries out on feed and food immediately prior to export to the European Union and such approval is only granted following audit showing that they are sufficiently effective and efficient to replace or reduce the documentary, identity and physical checks laid down in EU law. In 2007 Canada submitted an application to the Commission for approval of pre-export checks performed by the Canadian Grain Commission, in this instance the competent authority of Canada, for ochratoxin A contamination in wheat (common and durum) and wheat flour intended for export to the EU. This has been assessed and approved. In consequence Member States can reduce the frequency of sampling and analysis on those commodities provided each consignment is accompanied by a report containing the results of sampling and analysis performed in accordance with the provisions of Commission Regulation (EC) No 401/2006 laying down methods of sampling and analysis or with equivalent requirements, by a laboratory approved for that purpose by the Canadian Grain Commission. There are also certain administrative details that must be met.[10]

Zearalenone

No further developments this quarter

Other regulated contaminants

Arsenic

In September 2011 publicity[11] about the amount of arsenic in the apple juice arose in the USA. FDA moved quickly to establish confidence in the safety of apple juice. [12]

[10] Commission Implementing Regulation (EU) No 844/2011 of 23 August 2011 approved the pre-export checks carried out by Canada on wheat and wheat flour as regards the presence of ochratoxin A http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:218:0004:0007:EN:PDF accessed 08.11.11

[11] E.g. Consumer Reports 14 Sept 2011, available at http://news.consumerreports.org/home/2011/09/debate-grows-over-arsenic-in-apple-juice.html Accessed 06.01.12

[12] FDA, 2011, Apple Juice: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm271394.htm Accessed 06.01.12

Cadmium and Lead

See below for revisions on sampling and analysis, Regulation (EC) No 333/2007 on sampling and analysis amended by Commission Regulation (EU) No 836/2011 of 19 August 2011.

Dioxins, furans and PCBs

New action levels set

As part of an overall strategy to reduce the presence of dioxins, furans and PCBs in environment, feed and food maximum concentrations for dioxins, the sum of dioxins and dioxin-like PCBs were set for feed by Directive 2002/32/EC and for food by Regulation (EC) No 1881/2006. Action levels for dioxins and dioxin-like PCBs in food have been set by Commission Recommendation 2006/88/EC of 6 February 2006 on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs in order to stimulate a pro-active approach to reduce the presence of dioxins and dioxin- like PCBs in food. These action levels are a tool for competent authorities and operators to highlight those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination. Given that the sources of dioxins and dioxin-like PCBs are different, separate action levels are set for each; action thresholds for dioxins and dioxin-like PCBs in feed have been established by Directive 2002/32/EC. The World Health Organisation (WHO) has established toxic equivalency factors (TEFs) some of which were changed in 2005, notably for PCBs, octachlorinated congeners and pentachlorinated furans. The effects of these changes and the recent occurrence of the compounds of interest were reviewed by EFSA.[13] In the light of the review revised action levels taking into account the new TEF values, are required. In addition Commission experience appears to show that for some foodstuffs when the action levels are exceeded, it is not necessary to perform investigations where an exceedance is not related to a specific source of contamination that can be reduced or eliminated, but to overall environmental pollution. Therefore, action levels for these foodstuffs are no longer appropriate. Hence recommendation 2006/88/EC was replaced in August 2011 by Commission Recommendation 2011/516/EU setting action levels (in fat) for meat and meat products (excluding edible offal) of bovine animals, sheep, poultry, pigs, mixed fats, muscle meat of farmed fish and farmed fishery products, (on wet weight), raw milk and dairy products including butter fat, (on fat), hen eggs and egg products (on fat) and fruits, vegetables and cereals (on product).[14]

During the quarter EFSA was asked by the European Commission for a scientific opinion on the risk to public health related to the presence of high levels of dioxins and dioxin-like PCBs in liver from sheep and deer, possible reasons for this and whether dioxin and polychlorinated biphenyl (PCB) levels for liver should better be expressed on fresh weight rather than on a fat basis. The Panel on Contaminants in the Food Chain (CONTAM Panel) evaluated dioxin and PCB results from 332 sheep liver, 175 sheep meat and 9 deer liver samples submitted by eight European countries and estimated the exposure through consumption of sheep liver for adults (consumers only) and children. Regular consumption of sheep liver would result on average in an approximate 20 % increase of the median background exposure to dioxins and dioxin-like PCBs (DL-PCBs) for adults. On individual occasions, consumption of sheep liver could result in high intakes exceeding the tolerable weekly intake (TWI). The CONTAM Panel concluded that the frequent consumption of sheep liver, particularly by women of child-bearing age and children, may be a potential health concern. Additional intake of non dioxin-like PCBs (NDL-PCBs) from consumption of sheep liver does not add substantially to the total dietary intake. The range of fat content in sheep liver is considerably narrower than for a number of other food categories regulated in Regulation (EC) No 1881/2006. Therefore, the CONTAM Panel sees no need to change the basis for expression of results and maximum

[13] EFSA 'Results of the monitoring of dioxin levels in food and feed'
EFSA Journal 2010; 8(3):1385, http://www.efsa.europa.eu/en/ efsajournal/doc/1385.pdf

[14] Commission Recommendation 2011/516/EU of 23 August 2011 on the reduction of the presence of dioxins, furans and PCBs in feed and food http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:218:0023:0025:EN:PDF

levels solely for liver from fat weight to fresh weight basis. A lower activity of CYP1A enzymes in sheep than in cattle was identified as a possible reason for higher dioxin and DL-PCB levels in sheep liver.[15]

Furan formed during heat treatment of food and contributing to the sensory properties of the product has been shown to be carcinogenic in animal experiments. In order to monitor the presence of furan in food, European Commission Recommendation 2007/196/EC4 requests MS to collect data on heat-treated commercial food products, to allow a better estimate of dietary exposure. In September EFSA published the latest in a series of reports[16] providing an update of results submitted in 2010 added to previous data sampled and analysed between 2004 and 2009 and, in addition to previous reports, presents exposure estimates for different population groups. Data were sorted into 21 different food categories (5 coffee and 16 non-coffee categories) in accordance with previously reported results in the literature. In the current report, two main categories (jarred baby food and other) out of these 21 categories were further subcategorised into more homogenous subgroups in order to extract further information. In addition, coffee results were divided into results provided for different types of raw coffee and for coffee brews. The five coffee categories showed the highest furan content in comparison to the other food groups, with mean values of 45 µg kg^{-1} for brewed coffee, 394 µg kg^{-1} for instant coffee powder, 1,936 µg kg^{-1} for roasted ground coffee, 2,016 µg kg^{-1} for non specified coffee and 3,660 µg kg^{-1} for roasted coffee beans. The highest 95th percentile was determined for roasted coffee beans at 6,407 µg kg^{-1}. In the non-coffee categories mean values ranged between 3.2 µg kg^{-1} for infant formula and 49 µg kg^{-1} for jarred baby food "vegetables only", the latter also with the highest 95th percentile of 123 µg kg^{-1}. Exposure to furan was also estimated for different populations.

Inorganic tin

See below for revisions on sampling and analysis, Regulation (EC) No 333/2007 on sampling and analysis amended by Commission Regulation (EU) No 836/2011 of 19 August 2011.

3-MCPD

3-Chloropropane-1,2-diol (3-MCPD) is a food processing contaminant that belongs to a group of compounds called chloropropanols. 3-MCPD was first detected in acid-hydrolyzed vegetable proteins (acid-HVP) and related products, as a reaction product of phospholipids,glycerol with hydrochloric acid. 3-MCPD may also occur in other products such as bakery products, malt, cooked/cured fish or meat. The Scientific Committee on Food established a tolerable daily intake (TDI) of 2 µg/kg body weight (b.w.) in 2001, based on the a LOAEL for renal tubule hyperplasia of 1.1 mg/kg b.w. per day from a rat chronic study. (In 2002, the Joint FAO/WHO Expert Committee on Food Additives also established a provisional maximum TDI (PMTDI) of 2 µg/kg b.w). A European harmonised maximum level of 20 µg/kg^{-1} has been laid down for HVP and soy sauce. In December 2007 an official German food and feed control laboratory reported, for the first time, on findings of high levels of 3-MCPD esters in edible refined plant oils and fats as well as infant formula. In September 2011 a 90-day toxicological study by the University of Parma for EFSA was published on 3-MCPD and 3-MCPD dipalmitate in both male and female rats. Histopathological examination confirmed that the kidney and, in male rats, the testes are critical organs for 3-MCPD. The overall picture of nephrotoxicity was consistent with tubulotoxicity, which in female rats was severe enough to

[15] Scientific Opinion on the risk to public health related to the presence of high levels of dioxins and dioxin-like PCBs in liver from sheep and deer. EFSA Journal 2011;9(7):2297. [71 pp.] doi:10.2903/j.efsa.2011.2297. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2297.htm accessed 22.11.11

[16] European Food Safety Authority; Update on furan levels in food from monitoring years 2004-2010 and exposure assessment. EFSA Journal EFSA Journal 2011; 9(9):2347. [33 pp.] doi:10.2903/j.efsa.2011.2347. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2347.htm Accessed 05.01.12

cause acute renal failure in 20 to 50 % of animals receiving high doses of 3-MCPD. At such high doses, male rats showed extensive testicular toxicity. Detailed findings are reported.[17]

Also see below for revisions on sampling and analysis, Regulation (EC) No 333/2007 on sampling and analysis amended by Commission Regulation (EU) No 836/2011 of 19 August 2011.

Mercury

See below for revisions on sampling and analysis, Regulation (EC) No 333/2007 on sampling and analysis amended by Commission Regulation (EU) No 836/2011 of 19 August 2011.

Methods of sampling and analysis for contaminants

The revision of PAH limits (see above) required a consequent change in methods of analysis (in particular to set analytical performance criteria for PAH other than benzo(a)pyrene). Thus Commission Regulation (EU) No 836/2011 of 19 August 2011 amended Regulation (EC) No 333/2007 (which lays down analytical performance criteria only for benzo(a)pyrene) laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.[18] The European Union Reference Laboratory for Polycyclic Aromatic Hydrocarbons (EU-RL PAH) in collaboration with national reference laboratories carried out a survey that indicated that the analytical performance criteria currently applicable to benzo(a)pyrene are also suitable for the other three substances, benz(a)anthracene, benzo(b)fluoranthene and chrysene in relevant food matrices.[19] The amendment was also opportune to clarify some aspects of the specific requirements for analytical methods, in particular the requirements regarding the use of the performance criteria and the 'fitness-for-purpose' approach. The presentation of performance criteria was modified to be more uniform across all analytes. On sampling, experience acquired while implementing Regulation (EC) No 333/2007 revealed that in some cases the current sampling provisions may be impracticable or may lead to unacceptable economic damage to the sampled lot. For such cases, departure from the sampling procedures is now allowed, provided that sampling remains sufficiently representative of the sampled lot or sublot and that the procedure used is fully documented. For sampling at the retail stage, flexibility to depart from the sampling procedures existed already. The provisions for sampling at retail stage were therefore aligned with the general sampling procedures. More detailed provisions include prohibition on using plastic containers when sampling is carried out for PAH analysis.

Polycyclic aromatic hydrocarbons

Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs sets maximum levels for benzo(a)pyrene in a range of foodstuffs. As noted in previous editions of this work, EFSA has advised that benzo(a)pyrene is not a suitable marker

[17] E. Barocelli, A. Corradi, A. Mutti and P.G. Petronini, 2011, Comparison between 3-MCPD and its palmitic esters in a 90-day toxicological study Scientific report submitted to EFSA by University of Parma, Parma, Italy. Available at http://www.efsa.europa.eu/en/supporting/pub/187e.htm Accesed 06.01.12

[18] Commission Regulation (EU) No 836/2011 of 19 August 2011 amending Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:215:0009:0016:EN:PDF accessed 07.11.11

[19] JRC 59046 – 2010, Performance Characteristics of Analysis Methods for the Determination of Four Polycyclic Aromatic Hydrocarbons in Food Outcome of a survey conducted in 2010 among official food control laboratories, Compiled by Thomas Wenzl http://irmm.jrc.ec.europa.eu/EURLs/EURL_PAHs/whats_new/Documents/JRC_59046_performance_characteristics_pah4_survey_2010_final.pdf accessed 07.11.11

for the occurrence of polycyclic aromatic hydrocarbons in food and that a system of four specific substances (PAH4) would be the most suitable indicators of PAH in food. EFSA also concluded that a system of eight substances (PAH8) would not provide much added value compared to PAH4. The EFSA CONTAM Panel further concluded, using the Margin of Exposure (MOE) approach, that there is low concern for consumer health at the average estimated dietary exposures. However, for high level consumers the MOEs were close to or less than 10 000, which indicates a potential concern for consumer health. Thus the current system of using benzo(a)pyrene as the only marker for polycyclic aromatic hydrocarbons, was overturned by Commission Regulation (EU) No 835/2011 of 19 August 2011 amending Regulation (EC) No 1881/2006. New maximum levels for the sum of four substances (PAH4) (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) are introduced, whilst maintaining a separate maximum level for benzo(a)pyrene. The separate maximum level for benzo(a)pyrene is maintained to ensure comparability of previous and future data but this will be reassessed in the future. The recitals to the Regulation set out rationales for the revised limits.[20]

Other Contaminants

Acrylamide

No further developments this quarter

Polybrominated diphenyl ethers (PBDEs) in food

No further developments this quarter

Food Allergens

Risk factors for food allergy

The EFSA Panel on Plant Protection Products and their Residues (PPR) was asked to deliver a scientific opinion on the science behind dermal absorption. Although specifically targeted at Plant Protection Products and their Residues this may be of interest in view of current debates on the extent to which individuals may be sensitised to food allergens by a dermal route through broken skin.[21]

Food Additives

Aluminium in Food

See health claims section

Ban of whitening agents for flour in China

No further developments this quarter

[20] Commission Regulation (EU) No 835/2011 of 19 August 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in foodstuffs http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:215:0004:0008:EN:PDF accessed 07.11.11

[21] Outcome of the public consultation on the draft guidance on dermal absorption and the draft scientific opinion on the science behind the revision of the guidance document on dermal absorption. Publications 2011:175. [75 pp.]. Available at http://www.efsa.europa.eu/en/supporting/pub/175e.htm accessed 21.11.11

Calcium lignosulphonate

In 2010, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) provided a scientific opinion on the safety of calcium lignosulphonate when used as a carrier for vitamins and carotenoids intended to be added to foods for colouring and nutrient purposes. ANS asked for further information and the manufacturer provided a further toxicological report however the Panel considered that the new information does not address the questions raised by the Panel in the previous opinion. The Panel had considered that a chronic toxicity study of at least 12 months duration was needed to elucidate whether the reported histiocytosis in the mesenteric lymph nodes of the rats in the 90-day oral toxicity study could progress into a more adverse state with time and at lower doses. The Panel had considered that interim evaluation groups would be beneficial to the 12 months duration study design.[22]

Calcium Carbonate

The ANS Panel also in July 2011 provided an opinion re-evaluating the safety of calcium carbonate (E 170). The Panel agrees with previous evaluations that an ADI is unnecessary when considering the use of calcium carbonate as an additive. The Panel notes that the estimated exposures to calcium from all sources, including the use of calcium carbonate as a food additive, taken together with intakes of calcium from supplements and from food fortification are below the UL of 2500 mg/day for calcium from all sources established by the SCF in 2003. The Panel concludes that trace levels of adventitious nanoscale material within macroscale calcium carbonate are not of toxicological concern.[23]

Caramel Colouring

No further developments this quarter

Enzymes

EFSA's Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids Panel (CEF) adopted a 'Scientific Opinion on Guidance on the Submission of a Dossier on Food Enzymes' on 23 July 2009. In this guidance document the data required to conduct a risk assessment for food enzymes was described pursuant to Regulation (EC) No 1331/2008 on a common authorisation procedure for food additives, food enzymes and food flavourings and Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 which lays down the content of a dossier as well as the procedure to file a dossier for the safety evaluation of a food enzyme.[24]

Lycopene

Commission Directive 2011/3/EU amending Directive 2008/128/EC laying down specific purity criteria on colours for use in foodstuffs (OJ No. L13, 18.1.2011, p.59) revises the purity criteria for lycopene derived from red tomatoes, and permits the use of two new sources of lycopene in accordance with prescribed purity criteria. The domestic implementation of this in Northern

[22] Scientific Statement on the safety of calcium lignosulphonate (40-65) as a food additive. EFSA Journal 2011;9(7):2319 [10 pp.]. doi:10.2903/j.efsa.2011.2319. Available at: http://www.efsa.europa.eu/en/efsajournal/pub/2319.htm accessed 30.11.2011

[23] Scientific Opinion on reevaluation of calcium carbonate (E 170) as a food additive. EFSA Journal 2011;9(7):2318 [73 pp.].doi:10.2903/j.efsa.2011.2318. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2318.htm accessed 30.11.2011

[24] EFSA: Explanatory Note on the Guidance of the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes. Supporting Publication 2011:177. [18 pp.]. available at: http://www.efsa.europa.eu/en/supporting/doc/177e.pdf accessed 10.11.2011

Ireland and Wales was noted in the previous quarter and in this quarter in Scotland by The Food Additives (Scotland) Amendment (No. 2) Regulations 2011.[25]

Phthalates

The International Pharmaceutical Excipients Council (IPEC) Federation issued a statement on the use of phthalates in pharmaceutical products in response to reports of adulteration of certain nutritional supplements, vitamins, foods, and beverages imported from Taiwan. Two phthalates, di-ethyl hexyl phthlate (DEHP) and di-isononyl phthalate (DINP), which are commonly used as plasticizers for polyvinyl chloride (PVC)-based plastics, were found in certain adulterated products and subsequently recalled by Taiwan authorities. It is believed that the phthlates were added as a form of economically motivated adulteration as a low-cost replacement for palm oil.[26]

Sunset Yellow (E 110)

The European Commission is currently finalising a proposal to revise the maximum permitted levels for Sunset Yellow (E 110). The revision takes into account the conclusion of the Scientific Opinion of the ANS Panel related to the re-evaluation on the safety of that colour. The Panel reduced the ADI to 1 mg/kg (temporary ADI) and concluded that exposure is generally well over the revised ADI. In accordance with Article 31 of Regulation (EC) No 178/20024, on 29 July 2011 the European Commission requested EFSA to provide a new exposure assessment for children to Sunset Yellow FCF, based on currently available consumption data and revised uses of Sunset Yellow FCF proposed by the Commission and detailed in the document. The mean anticipated dietary exposure to Sunset Yellow FCF in European children (aged 1-14 years) range from 0.02 to 0.4 mg/kg bw/day, and the high level estimates range from 0.08 to 1.2 mg/kg bw/day. The main contributors to the total anticipated exposure to Sunset Yellow FCF are non-alcoholic flavoured drinks and desserts including flavoured milk products. For all scenarios the high level exposure estimates for children calculated with the proposed revised Maximum Permitted Levels are below the temporary ADI of 1 mg/kg bw/day for all European countries considered (maximum of 0.8 mg/kg bw/day) except for UK pre-school children who might slightly exceed the ADI in some scenarios (1.1 to 1.2 mg/kg bw/day).[27]

Food Contact Materials

Evaluation of recycling processes

Following the publication of the Regulation (EC) No 282/2008 of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and the relevant EFSA Guidelines on submission of a dossier for safety evaluation, many dossiers have been submitted to EFSA for evaluation dealing with recycling processes for polyethylene terephthalate (PET) food contact materials. These processes use as an input post consumer

[25] The Food Additives (Scotland) Amendment (No. 2) Regulations 2011 http://www.legislation.gov.uk/ssi/2011/305/made/data.pdf

[26] IPEC Federation Issues Statement of Phthalate Use, Jun 30, 2011, Patricia Van Arnum ePT--the Electronic Newsletter of Pharmaceutical Technology http://pharmtech.findpharma.com/pharmtech/article/articleDetail.jsp?id=729151&sk=3b85ca1515e70bf86341a7a469ec52fd

[27] European Food Safety Authority; Revised exposure assessment for Sunset Yellow FCF based on the proposed revised maximum permitted levels of use as a food additive. EFSA Journal 2011;9(9):2349. [10 pp.] doi:10.2903/j.efsa.2011.2349. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2349.htm Accessed 06.01.12

PET to produce recycled[28] PET intended for food contact applications. The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) evaluated these PET recycling processes and has developed criteria specific to this type of plastic which are used during the evaluation process. CEF has published the risk assessment approach it uses and provides arithmetic values for the criteria specific to the evaluation of recycling processes for PET intended to be used in food contact materials.

Hexabromocyclododecanes (HBCDDs)- flame retardants

HBCDDs are stereoisomers of 1,2,5,6,9,10-hexabromocyclododecane. Technical HBCDD predominantly consists of three stereoisomers (α-, β- and γ-HBCDD) present in relative amounts of 9-13 % α-HBCDD, <0.5-12 % β-HBCDD and 72-90 % γ-HBCDD. Also δ- and ε-HBCDD may be present in the technical product, although at very low concentrations. The HBCDD stereoisomers occur as enantiomer pairs. HBCDDs constitute an important and widely used group of additive flame retardants primarily used in expanded and extruded polystyrene applied as construction and packing materials, and also used in textiles. Concentrations in products are usually in the range between 0.7 % and 3.0 % by weight. As they are mixed into polymers and not chemically bound to the plastic or textiles, HBCDDs might leach from the products into the environment and likewise in biota and in food and feed. Technical HBCDD has been on the market since the 1960s but the use in insulation boards started in the 1980s. EFSA was asked by the European Commission to deliver a scientific opinion on HBCDDs in food. Data from the analysis of HBCDDs in 1,914 food samples were provided to EFSA by seven European countries, covering the period from 2000 to 2010. The CONTAM Panel selected α-, β- and γ-HBCDD to be of primary interest. HBCDDs are not genotoxic but CONTAM identified neurodevelopmental effects on behaviour as the critical endpoint, and derived a benchmark dose lower confidence limit for a benchmark response of 10 % ($BMDL_{10}$) of 0.79 mg/kg body weight. Due to the limitations and uncertainties in the current data base, the CONTAM Panel concluded that it was inappropriate to use this BMDL to establish a health based guidance value, and instead used a margin of exposure (MOE) approach for the health risk assessment of HBCDDs. Since elimination characteristics of HBCDDs in animals and humans differ, the Panel used the body burden as starting point for the MOE approach. The CONTAM Panel concluded that current dietary exposure to HBCDDs in the European Union does not raise a health concern. Also additional exposure, particularly of young children, to HBCDDs from house dust is unlikely to raise a health concern.[29]

Migration of mineral oils from recycled newspapers

No further developments this quarter

Non-Plastic Food Contact Materials

Noting that some recent incidents originated from non-plastic parts of food contact materials e.g. coatings, paper and board, adhesives, printing inks and rubber EFSA elected to gather further information in this area. These materials are not covered by a specific regulation and thousands of substances are used to manufacture them which have not been evaluated for their safety at the EU level. An EFSA Scientific Cooperation (ESCO) Working Group was set up to collect evaluations available in Member States, to prepare inventory lists of evaluated substances and classify them according to the way they were evaluated (guidelines, risk assessment background), identify gaps and strengths in different approaches, establish the principles of setting the priorities for further evaluations and identify the most knowledgeable

[28] Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food. EFSA Journal 2011;9(7):2184. [25 pp.] doi:10.2903/j.efsa.2011.2184. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2184.htm accessed 21.11.11

[29] Scientific Opinion on Hexabromocyclododecanes (HBCDDs) in Food. EFSA Journal 2011;9(7):2296. [118 pp.] doi:10.2903/j.efsa.2011.2296. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2296.htm accessed 22.11.11

experts in the field, who could be mobilized in case of further need. The final ESCO inventory list contains 3000 substances. The WG divided these substances into two groups, according to their date of evaluation: after (list A) and before (list B) the publication of SCF Guidelines for Food Contact Materials (1991). List A contains 320 substances.

The ESCO WG has proposed strategies for both prioritization of the evaluations of substances and for providing preliminary advice in case of emergency situations. Where toxicological data are available on substances with similar chemical structure, read-across can be used to draw preliminary conclusions on the toxicity of the substance. (Q)SAR approaches can also be useful. Where little or no toxicological data are available, human exposure threshold approaches, based on the chemical structure of the substances (such as the Threshold of Toxicological Concern - TTC – approach) can be used. A table with these human exposure thresholds below which there is a very low probability of adverse effects to human health is given indicatively in this report. EFSA emphasized that the above approaches are not designed to replace full risk assessment. These principles may be of value to industry to define which studies should be undertaken in priority. Evaluation of possible dietary exposure was also considered.[30]

Extraction Solvents in Food

The Extraction Solvents in Food Regulations 1993 (S.I. 1993/1658) were amended by the Extraction Solvents in Food (Amendment) (England) Regulations 2011[31] to implement in England Commission Directive 2010/59/EU amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ No. L225, 27.8.2010, p.10). The amendments to the 1993 Regulations consist of —
(a) the listing in Schedule 2 of dimethyl ether as an extraction solvent that may be used in the preparation of defatted animal protein products (*regulation 2(2)*); and
(b) the inclusion in Schedule 3 (which concerns the use of extraction solvents in the preparation of natural flavourings) of methanol and propanol-2-ol, with associated prescribed residue limits (*regulation 2(3)*).

Similar amendments were made in Northern Ireland, Wales and Scotland. [32]

Natural Mineral and other Bottled Waters

No further developments this quarter

Pesticides

Further changes were made in the quarter on maximum residue levels. Commission Regulation (EU) No 812/2011 of 10 August 2011 amended Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethomorph, fluopicolide, mandipropamid, metrafenone, nicotine and spirotetramat in or on certain products. Commission Regulation (EU) No 813/2011 of 11

[30] Report of ESCO WG on non-plastic Food Contact Materials. Supporting Publications 2011:EN-139 [60 pp.]. Available at http://www.efsa.europa.eu/en/supporting/pub/139e.htm Accessed 21.11.11
[31] The Extraction Solvents in Food (Amendment) (England) Regulations 2011 available at http://www.legislation.gov.uk/uksi/2011/1738/made/data.pdf accessed 07.11.11
[32] The Extraction Solvents in Food (Amendment) (Northern Ireland) Regulations 2011
http://www.legislation.gov.uk/nisr/2011/284/made/data.pdf
The Extraction Solvents in Food (Amendment) (Wales) Regulations 2011
http://www.legislation.gov.uk/wsi/2011/1849/made/data.pdf
The Extraction Solvents in Food Amendment (Scotland) Regulations 2011
http://www.legislation.gov.uk/ssi/2011/306/made/data.pdf

August 2011 amended Annexes II and III to the same Regulation for acequinocyl, emamectin benzoate, ethametsulfuron-methyl, flubendiamide, fludioxonil, kresoxim-methyl, methoxyfenozide, novaluron, thiacloprid and trifloxystrobin in or on certain products.[33]

In September 2011, EFSA issued a Technical Report on the activities of the Pesticide Risk Assessment Peer Review (PRAPeR) Networks in 2010. EFSA has set up two Networks with Member State organisations in the area of pesticides:

- the Pesticide Steering Committee (PSC) which was established to manage and plan the overall pesticide risk assessment and consider ways to further streamline the process;
- the Networking Group on Pesticide Monitoring, which is intended to strengthen the collaboration between Member States, the countries of the European Free Trade Association (EFTA) which have an obligation to submit results of their national pesticide monitoring programmes, the European Commission and EFSA.

In 2010, the PSC has contributed to the planning of the peer review of the rapporteur Member States' assessments of active substances in the framework of Directive 91/414/EEC3. This planning, as well as the systematic monitoring of progress in the PSC, has permitted EFSA to prepare its part of the risk assessment process as adequately as possible, to manage the high workload and yet meet the legal deadlines.

An important issue for the PSC in 2010 was the preparation for the full applicability of Regulation (EC) No 1107/20094. Consideration was given to setting MRLs, coordination with the European Chemicals Agency in the area of the classification of active substances, evaluation of basic substances and the development of guidance by EFSA for the selection of scientific peer-reviewed open literature to be added to the dossiers.

The PSC has also been the forum for the identification and the prioritisation of guidance documents to be developed or updated, in particular by the EFSA Panel for the Plant Protection products and their residues.

The Networking Group on Pesticide Monitoring supported the development of the new format to submit the results of the national pesticide monitoring activities (SSD-Standard Sample Description). The Networking group reviewed and adopted two EFSA guidance documents on the use of the Standard Sample Description. The work done with the Networking Group allowed the successful establishment of the largest database on pesticide residues in Europe (data and information about ca. 14 million analytical determinations in 2010). The implementation of the new format (SSD) to report pesticide residues data improved the quality of the data submitted and in consequence improved the accuracy of the actual exposure assessment of consumers via food containing pesticide residues.

Individual risk assessments are not detailed here, see http://www.efsa.europa.eu/en/panels/pesticides.htm?wtrl=01 for more information.

Veterinary Residues

The spread of antimicrobial resistance continues to lead to pressure to decrease the total antimicrobial use in animal production in the EU. An emerging issue concerns the increased occurrence of bacterial strains producing extended-spectrum beta (β)-lactamases (ESBLs) and/or acquired AmpC β-lactamases, affecting 3rd- and 4th-generation cephalosporin and

[33] Regulation (EU) No 812/2011 of 10 August 2011 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:208:0001:0022:EN:PDF and Regulation (EU) No 813/2011 of 11 August 2011 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:208:0023:0079:EN:PDF

monobactam antimicrobials. These antimicrobials are important in human and veterinary medicines.[34]

Residue Monitoring Results 2009

No further developments this quarter

Nanomaterials

No further developments this quarter

Toxicology

The EFSA Panel on Plant Protection Products and their Residues (PPR) was asked to deliver a scientific opinion on the science behind the revision of the guidance document on dermal absorption and a revised guidance document on dermal absorption. The process of consultation and comments received were reviewed by EFSA in a useful publication in July.[35]

Genotoxicity

Information on genotoxicity (the extent to which an agent damages cellular DNA, resulting in mutations or cancer) is a key component in risk assessment of chemicals in general and has been used in relation to food and feed safety for many years. Genotoxicity information is also essential for risk assessment of natural and environmental contaminants in food and feed. During the work of the EFSA Scientific Committee on the welfare of experimental animals in 2007, it became apparent that, although there are some similarities in the requirements for genotoxicity testing, they do differ between the various EFSA Panels and the types of substance being evaluated. There are differences both in the recommended basic battery of tests and in recommendations for any necessary follow-up tests. It was also noted that existing EFSA guidance on strategies for follow-up of *in vitro* positive or equivocal results is often very general. Thus, in a report[36] published in September 2011 the EFSA Scientific Committee reviewed the current state-of-the-science on genotoxicity testing and provided a commentary and recommendations on genotoxicity testing strategies. A step-wise approach is recommended for the generation and evaluation of data on genotoxic potential. The report took into account responses to a public consultation.[37]

Kava

Two papers emerged in the quarter on Kava, rhizomes and roots of the South Pacific plant *Piper methysticum* used to make dietary supplements. The reportedly psychoactive, anxiolytic, relaxing, and recreational ingredients are the kavalactones kavain, dihydrokavain,

[34] EFSA Panel on Biological Hazards (BIOHAZ); Scientific Opinion on the public health risks of bacterial strains producing extended-spectrum β-lactamases and/or AmpC β-lactamases in food and food-producing animals. EFSA Journal 2011;9(8):2322. [95 pp.] doi:10.2903/j.efsa.2011.2322. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2322.htm accessed 05.01.12

[35] Outcome of the public consultation on the draft guidance on dermal absorption and the draft scientific opinion on the science behind the revision of the guidance document on dermal absorption. Publications 2011:175. [75 pp.]. Available at http://www.efsa.europa.eu/en/supporting/pub/175e.htm accessed 21.11.11

[36] EFSA Scientific Committee; Scientific Opinion on genotoxicity testing strategies applicable to food and feed safety assessment. EFSA Journal 2011;9(9):2379. [68 pp.] doi:10.2903/j.efsa.2011.2379. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2379.htm Accessed 06.01.12

[37] Public Consultation, EFSA, http://www.efsa.europa.eu/en/supporting/pub/189e.htm Accessed 06.01.12

methysticin, dihydromethysticin, yangonin, and desmethoxyyangonin, but there is little evidence that these kavalactones or the non-kavalactones pipermethystine and flavokavain B are responsible for known adverse hepatic reactions. A major review of scientific knowledge on kava has left unsolved the mystery of why Pacific Island people can consume it safely, while people in the United States, Europe, and other Western cultures sometimes experience toxic effects. Aqueous kava root preparations have been consumed in the South Pacific as an apparently safe ceremonial and cultural drink for centuries. However, several reports of hepatotoxicity have been linked to the consumption of kava extracts in Western countries, where mainly ethanolic or acetonic extracts are used. In 2001, reports of liver damage among Westerners who took kava supplements gained widespread attention. Many Western countries, including the United States, the United Kingdom, and Canada, ban or regulate the sale of kava products. A recent review of 85 scientific studies on kava toxicity found no consensus on kava toxicity. The toxicity of the individual kava lactones has been assessed without firm conclusions. Inhibition or induction of the major metabolizing enzymes, which might result in drug interactions, has also gained attention, but ambiguous results have been reported. On the basis of the chemical structures of kava constituents, the formation of reactive metabolites has also been suggested as an explanation of toxicity. Furthermore, skin rash is a side effect in kava consumers, which may be indicative of the formation of reactive metabolites and covalent binding to skin proteins leading to immune-mediated responses. Reactive metabolites of kava lactones have been identified in vitro as glutathione (GSH) conjugates and in vivo as mercapturates excreted in urine. Addition of GSH to kava extracts has been shown to reduce cytotoxicity in vitro, which suggests the presence of inherently reactive constituents. Only a few studies have investigated the toxicity of the minor constituents present in kava extract, such as pipermethystine and the flavokavains, where some have been shown to display higher in vitro cytotoxicity than the lactones. To date, there remains no indisputable reason for the increased prevalence of kava-induced hepatotoxicity in Western countries.[38] However it may be that poor quality of the kava material was responsible for the liver toxicity. Focusing on existing chemical, agricultural, manufacturing, nutritional and regulatory kava quality standards other authors found major shortcomings that might explain quality problems. They suggested a uniform, internationally accepted quality standard for kava in the interest of consumers, kava farmers, pharmaceutical manufacturers, and regulators. The initial step would be the establishment of Pan-Pacific kava quality legislation as an important part of the proposed Kava Quality Standardization Code.[39]

Transmissible Spongiform Encephalopathys, TSE/BSE

An editorial in the EFSA journal provided, in September 2011, an overview of BSE and the TSE roadmap. Interestingly the writer choose a George Bernard Shaw quotation to open his piece. *"I dread success. To have succeeded is to have finished one's business on earth....I like a state of continual becoming, with a goal in front and not behind."*

The editorial highlighted that the decline of the BSE epidemic seen by 2005 led to consideration of some relaxation of costly BSE control measures as depicted in the EU TSE Roadmap and will inevitably be followed by further relaxation. It remains critical that current levels of consumer protection are maintained and all future changes from well established and highly effective current risk management measures are based upon sound scientific advice that EFSA will continue to provide. For the future, for Atypical BSE, the most widely accepted hypothesis is that of a spontaneously arising ("sporadic") disease in relatively old bovines. If this holds true, it will be impossible to eradicate such a disease which originates *de novo*. The writer speculates that probably we then have to live forever with a ban on SRMs, in particular the central nervous system (CNS), of older cattle. Given our insufficient knowledge

[38] Constituents in Kava Extracts Potentially Involved in Hepatotoxicity: A Review
Line R. Olsen, Mark P. Grillo and Christian Skonberg, Chem. Res. Toxicol., DOI: 10.1021/tx100412m, Publication Date (Web): April 20, 2011, http://www.eurekalert.org/pub_releases/2011-07/acs-tum071311.php

[39] Rolf Teschkea and Vincent Lebotb, Proposal for a Kava Quality Standardization Code, Food and Chemical Toxicology, 49, 2011, 2503-2516, doi:10.1016/j.fct.2011.06.075

about the true prevalence of atypical animal prion strains in the field, it will be important to continue and improve the systematic surveillance of animal TSEs, and to refine our diagnostic and laboratory methods and experiments. As some scientific data suggest that there is probably no absolute molecular barrier to transmission of TSE agents between mammalian species, the issue of a zoonotic potential of prions is likely to remain. For human TSEs including sporadic CJD, it will be important to continue systematic surveillance that should be able, as clearly shown with vCJD in the past, eventually to identify emerging new phenotypes or new prion strains. Presciently, the writer suggestes that at a time when many scientists and most decision makers are no longer interested in prions and their risk, it will be prudent to stay vigilant, although this must be in a way that is balanced with other risks to human and animal health. In the risk assessment area, this will continue to be a challenge for EFSA in the years to come.[40]

Food Hygiene

Antimicrobial Resistance

The spread of antimicrobial resistance continues to be of concern with an emerging issue being the increased occurrence of bacterial strains producing extended-spectrum beta (β)-lactamases (ESBLs) and/or acquired AmpC β-lactamases, thus making it difficult to treat severe infections in humans, and their possible link to food or food producing animals. Many different kinds of bacteria are able to produce such enzymes, which deteriorate the effects of 3rd- and 4th-generation cephalosporin and monobactam antimicrobials. These antimicrobials are considered by WHO to be critically or highly important medicines for humans and are also listed as antimicrobials of veterinary importance by the World Organisation for Animal Health (OIE). The bacterial species most commonly identified with genes encoding relevant β-lactamases are *Escherichia coli* and non-typhoidal *Salmonella*. Prioritisation and risk assessment is complex and hampered by lack of data, but it is considered that a highly effective control option would be to stop all uses of cephalosporins/systemically active 3rd/4th generation cephalosporins, or to restrict their use (use only allowed under specific circumstances). As co-resistance is an important issue, it is also of high priority to decrease the total antimicrobial use in animal production in the EU.[41]

Campylobacter in broiler meat production

See below, EU Trends.

EU Trends

EU MS collect data on zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks. EFSA analyses these data in preparing the annual zoonoses European Union Summary Report. A critical review of the statistical analysis of time trends was carried out previously. In September 2011 EFSA updated a Part II Report giving examples of application of spatial analysis to investigate the geographic distribution of zoonotic agents. Data on *Salmonella* Infantis in breeding pig holdings, *Campylobacter*-colonized broiler slaughter batches) and *Salmonella* infected laying hen holdings were studied. The occurrence of *Salmonella* Infantis-positive holdings was not randomly distributed across the EU while for the

[40] Budka H; Editorial: The European Response to BSE: A Success Story. EFSA Journal 2011; 9(9):e991. [3pp.] doi:10.2903/j.efsa.2011.e991. Available at http://www.efsa.europa.eu/en/efsajournal/pub/e991.htm Accessed 05.01.12

[41] EFSA Panel on Biological Hazards (BIOHAZ); Scientific Opinion on the public health risks of bacterial strains producing extended-spectrum β-lactamases and/or AmpC β-lactamases in food and food-producing animals. EFSA Journal 2011;9(8):2322. [95 pp.] doi:10.2903/j.efsa.2011.2322. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2322.htm accessed 05.01.12

other microorganisms the situation was less clear. The reports concentrate on examination and validation of the statistical techniques applied. Communication of complex statistical techniques to public health professionals and to the public was indicated as a critical issue. Suggestions for minimum sample sizes and number of time points needed for identifying trends of zoonotic agents in the European Union are also provided.[42]

Foodbourne Virus

A proportion of infectious intestinal disease is caused by viruses although at the EU-level it is unknown how much viral disease can be attributed to foodborne spread. Food may be contaminated by virus during all stages of the food supply chain, and transmission can occur by consumption of food contaminated during the production process (primary production, or during further processing), or contaminated by infected food handlers. Viruses do not multiply in foods, but may persist for extended periods of time as infectious particles. A review of the biology, epidemiology, diagnosis and public health importance of foodborne viruses was published by EFSA in July 2011. Data needs to support a risk assessment were also identified. In addition possible control options and their anticipated impact to prevent or reduce the number of foodborne viral human infections were identified, including the scientific reasons for and against the establishment of food safety criteria and process hygiene criteria for viruses for certain food categories. The report recommends focusing controls on preventive measures to avoid viral contamination rather than trying to remove/inactivate these viruses. Also, it is recommended to introduce a microbiological criteria for viruses in bivalve molluscs, unless they are labelled “to be cooked before consumption” and introduction of virus microbiological criteria for classification of bivalve molluscs production areas should be considered. A virus monitoring programme for compliance with these criteria should be risk based according to the findings of a sanitary survey.[43]

Lactic Acid Treatment

One of the options that might reduce food poisoning is to treat carcasses to reduce their microbiological load. Studies evaluating the safety and efficacy of lactic acid treatment for decontamination of beef carcasses, cuts and trimmings were assessed by EFSA during the quarter. Treatments considered consisted of using 2 % to 5 % lactic acid solutions at temperatures of up to 55 °C applied either by spraying or misting. EFSA concluded that these treatments are of no safety concern provided the substance used complies with the European Union specifications for food additives. It was also concluded that, although variable, microbial reductions achieved by lactic acid treatment of beef are generally significant compared to untreated or water treated controls. Development of enzymatic resistance to therapeutic antimicrobials as a result of exposure to lactic acid and the possibility of mutational changes resulting in the development of resistance to therapeutic antimicrobials are unlikely. It was recommended that, according to HACCP principles, during use, business operators verify lactic acid concentration, temperature of application and other factors affecting its efficacy as a decontaminating agent and validate the antimicrobial efficacy under their specific processing conditions. No studies applying water rinsing of lactic acid after treatment of beef were submitted, and therefore, this issue was not addressed.[44]

---

[42] European Food Safety Authority; Statistical analysis of temporal and spatial trends of zoonotic agents in animals and food, Part II: Applications of spatial analysis and further developments of temporal analysis. EFSA Journal, 2011; 9(8):2331. [72 pp.]. doi:10.2903/j.efsa.2011.2331. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2331.htm Accessed 05.01.12

[43] EFSA Panel on Biological Hazards (BIOHAZ); Scientific Opinion on An update on the present knowledge on the occurrence and control of foodborne viruses. EFSA Journal 2011;9(7):2190. [96 pp.] doi:10.2903/j.efsa.2011.2190. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2190.htm accessed 11.11.11

[44] Scientific Opinion on the evaluation of the safety and efficacy of lactic acid for the removal of microbial surface contamination of beef carcasses, cuts and trimmings. EFSA Journal 2011;9(7):2317. [35 pp.] doi:10.2903/j.efsa.2011.2317. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2317.htm accessed 22.11.11

Risk Characterisation

Microbiological risk assessment (MRA) is a tool that can be used in the management of the risks posed by foodborne pathogens, including the elaboration of standards for food in international trade. FAO and WHO have undertaken a programme of activities on MRA at international level and have published a Microbiological Risk Assessment series that provides a range of data and information to those who need to understand or undertake MRA. It comprises risk assessments of particular pathogen–commodity combinations, interpretative summaries of the risk assessments, guidelines for undertaking and using risk assessment, and reports addressing other pertinent aspects of MRA.[45]

Salmonella

Salmonella spp. is one of the most common and widely distributed foodborne pathogens in the European Union.

EFSA has published a report from Vose Consulting (US) on the development of a quantitative microbial risk assessment model for risk to consumers from *Salmonella* spp. in broiler meat produced in the EU. The approach used is reported to follow Bayesian statistics.[46] Also published in the quarter was an analysis of the baseline survey on Salmonella in breeding pigs in the EU, 2008 - Part B: factors associated with Salmonella pen positivity[47] and a report on the Public health impact of a new target for the reduction of Salmonella in broiler flocks.[48]

Surveillance programmes and intervention strategies to control foodborne salmonellosis have been implemented in EU Member States. However a precise evaluation of the effect of such interventions is difficult, partly due to the lack of information of the public-health impact of specific sources on the incidence of foodborne infections. To identify and prioritize effective food safety interventions, a report in August 2011 to EFSA from Technical University of Denmark attempted to quantify the contribution of important food sources to the burden of human salmonellosis. Two methods were applied, a microbial subtyping approach and an analysis of data from outbreak investigations. Results showed that the relative contribution of food-animal sources varied between regions and countries. The laying hen reservoir was estimated to be the most important source in the EU, contributing 43.8% (95% Credibility Interval (CI) 43.2 – 44.4%) of cases attributed to this source, followed by pigs (26.9%, 95% CI 26.3-27.6%). Turkeys and broilers were estimated to be less important sources of *Salmonella*, contributing 4.0% (95% CI 3.8-4.3%) and 3.4% (95% CI 3.1-3.7%), respectively. A total of 9.2% of all salmonellosis cases were reported as being travel-related, (more in northern Europe) and 3.6% of cases were reported as being part of outbreaks with unknown source. Nine percent of cases could not be attributed to any source included in the model. Some reservoirs of *Salmonella* (e.g. cattle/beef) were not included in the model due to lack of data or poor data quality and suggestions were made to improve data quality. The analysis of data from outbreak investigations attributed salmonellosis to 19 food sources and water. Eggs were estimated to be the most important source of disease in the study period, followed by pork, chicken, the general category “meat and poultry”, and dairy products. An analysis by

[45] Microbiological Risk Assessment Series, 17, Risk characterization of Microbiological hazards in food Guidelines, World Health Organization, Food and Agriculture Organization of the UN, 2009, Available at: http://www.who.int/foodsafety/publications/micro/MRA17.pdf Accessed 06.01.12

[46] D. Vose, T. Koupeev and K Mintiens, 2011, A Quantitative Microbiological Risk Assessment of Salmonella spp. in broiler, (Gallus gallus) meat production. Available at http://www.efsa.europa.eu/en/supporting/pub/183e.htm accessed 22.11.11

[47] Scientific Report of EFSA - Published: 26 July 2011 Analysis of the baseline survey on *Salmonella* in breeding pigs in the EU, 2008 - Part B: factors associated with *Salmonella* pen positivity noted but not accessed

[48] Scientific Opinion of the BIOHAZ Panel - Published: 26 July 2011 Public health impact new target for the reduction of *Salmonella* in broiler flocks noted but not accessed

year showed that the contribution of eggs decreased in 2009, and the proportion of disease attributed to remaining sources varied over the years and between regions. Despite data limitations and the resulting uncertainty in the results, the obtained source attribution estimates are considered useful for delineating risk management strategies.[49] See also, EU Trends, above.

Shiga toxin/verotoxin-producing *Escherichia coli* (STEC/VTEC)

The largest outbreak of haemolytic uremic syndrome (HUS) ever reported started in Germany in May 2011 and included several cases from other EU and non-EU countries, caused by Shiga-toxin producing *Escherichia coli*- bacteria (STEC), serotype O104:H4. Between the 1st of May and the 28th of June 2011, 838 Haemolytic Uremic Syndrome (HUS) cases and 3,091 STEC cases with diarrhoea were reported, with 47 fatalities. Preliminary reports on the outbreak were collated in our previous (April – June) report. On Friday the 24th of June, France reported a cluster of patients with bloody diarrhoea, after having participated in an event near Bordeaux on the 8th of June. Infection with *E. coli* O104:H4 was confirmed for four patients with HUS. Six of the cases reported having eaten sprouts of fenugreek, rocket and mustard at the event and investigation revealed that the suspected items had been privately produced in small quantities by the organiser of the event from seeds bought at an approved garden centre, and were not imported from the sprout producer implicated in the outbreak in Germany. EFSA was urgently requested by the Commission to initiate a comprehensive tracing back exercise (followed by tracing forward) to identify the source of the two outbreaks and contribute to identifying appropriate risk mitigating measures regarding potential further outbreaks. These further investigations particularly aimed at determining whether the origin of the suspected sprout-seeds from the French cluster was linked to the large outbreak in northern Germany. On 5th July 2011 EFSA reported the steps taken in the trace back process and other activities already undertaken. Interestingly, given the possible severe health impact of exposure to a small quantity of contaminated material, and, in the absence of information regarding the source and means of contamination and possible cross-contamination, EFSA considered it appropriate to consider all lots of fenugreek from the identified exporter as suspect. In this regard, they suggested any negative test results from the microbiological tests carried out on seeds were not interpreted as proof that a batch is not contaminated with STEC O104:H4 since these results depend on and may be limited by both the analytical and diagnostic performance characteristics as well as by the nature of the sampling plan. The report is one of many elements contributing to the investigation of the cause of this outbreak, and should not be considered in isolation. The findings of this study were consistent with other investigations conducted thus far. Specifically, it supports the hypothesis that the outbreaks in Germany and France are linked, and are due to the import of fenugreek seeds, which became contaminated with STEC O104:H4 at some point prior to leaving the Importer. The contamination of seeds with the STEC O104:H4 strain reflects a production or distribution process which allowed contamination with faecal material of human and/or animal origin. Where exactly this took place was still an open question. Typically such contamination could occur during production at the farm level. While contamination at subsequent steps in, up to, and including at the Importer cannot be excluded, it is highly unlikely that contamination could have taken place during transport of the sealed container. The report made recommendations to prevent further consumer exposure to seeds from the lots of concern. For example a trace back investigation on the incriminated lots of fenugreek seeds in the third country from which they were exported to the Member States and third countries should initiate or complete forward tracing of companies receiving the suspect lots. In the medium term, EFSA recommends using the experience of the back tracing of sprout-seeds in Europe to develop and validate appropriate tools for the generic methodology of trace back at the EU level.[50]

[49] Sara M. Pires, Leonardo de Knegt and Tine Hald, 2011, Estimation of the relative contribution of different food and animal sources to human Salmonella infections in the European Union. Scientific / technical report submitted to EFSA from the National Food Institute, Technical University of Denmark. Available at http://www.efsa.europa.eu/en/supporting/pub/184e.htm Accessed 06.01.12

[50] European Food Safety Authority; Tracing seeds, in particular fenugreek (Trigonella foenum-graecum) seeds, in relation to the Shiga toxin-producing E. coli (STEC) O104:H4 2011 Outbreaks in

Consumer Choice and Prevention of Fraud

Animal Welfare

EFSA published three externally sourced reports on pig welfare in the quarter and although this topic bears mainly on labelling issues measurement is also a feature as one recommendation made was that ammonia levels in pig housing should not exceed 20ppm.[51] One of the reports looked at animal based indicators to assess the welfare of livestock animals as an extension to resource-based parameters, i.e. measures taken regarding the environment in which the animals are kept. Animal-based measures aim to directly measure the actual welfare status of the animal and thus include indirectly the effect of resource and management factors.[52]

Composition and Labelling

Fruit Juices and Fruit Nectars

No further developments this quarter

Fruit juice authenticity

No further developments this quarter

Organic Food

No further developments this quarter

Fish parasites

Public Analysts occasionally need to evaluate the significance of parasites such as cod worm in fish fillets and will be interested in an EFSA report on fish parasites from the Baltic. EFSA report that for fishery products caught from fishing grounds in the Baltic Sea, four groups of viable parasites present possible health risks, *Anisakis simplex* (*sensu stricto*), *Contracaecum osculatum* (*sensu stricto*), *Pseudoterranova decipiens* (*sensu stricto*) and *Diphyllobothrium* spp. Since *A. simplex* and *Pseudoterranova decipiens* have been found in fishery products in International Council for the Exploration of the Sea (ICES) subdivisions 22, 23, 24, 25, 26, public health risks due to the presence of these parasites cannot be excluded in any fishery products caught from these areas. Migrating fish from areas where *A. simplex*, and to a lesser degree *P. decipiens*, occur may carry these parasites and reach the northern Baltic, therefore, public health risks due to parasites in all migrating fish (including salmon) in the Baltic Sea

---

Germany and France. Available at http://www.efsa.europa.eu/en/supporting/doc/176e.pdf accessed 11.11.11

[51] Hans Spoolder, Marc Bracke, Christine Mueller-Graf and Sandra Edwards, TECHNICAL REPORTs submitted to EFSA, Preparatory work for the future development of animal based measures for assessing the welfare of pigs,
Report 1: Preparatory work for the future development of animal based measures for assessing the welfare of sow, boar and piglet including aspects related to pig castration Report 2: Preparatory work for the future development of animal based measures for assessing the welfare of weaned, growing and fattening pigs including aspects related to space allowance, floor types, tail biting and need for tail docking, available at http://www.efsa.europa.eu/en/supporting/pub/178e.htm and http://www.efsa.europa.eu/en/supporting/pub/181e.htm accessed 22.11.11

[52] Review of methodologies applicable to the validation of animal based indicators of welfare, available at http://www.efsa.europa.eu/en/supporting/pub/171e.htm accessed 30.11.2011

cannot be excluded. *C. osculatum* occurs in fish throughout all areas of the Baltic Sea. However, at present it is not possible to assess the public health importance of viable *C. osculatum* larvae in fishery products. *Diphyllobothrium* spp. occurs in fish species in brackish waters of Baltic Sea. Hence all freshwater fish as well as migrating fish, including sea trout and whitefish, are of public health importance if consumed raw, since they may carry viable parasites. More research is needed to elucidate the importance of *C. osculatum* from fish as a source of human infection, including pathogenicity of this parasite and the anatomic distribution of the parasite in edible parts of the fish. In order to definitively identify species of anisakids, genetic/molecular methods should be more widely applied to material from all hosts of the Baltic Sea. Surveillance of anisakiasis and other parasitic infections in the human population in Baltic Sea countries should be improved.[53]

Food Irradiation

No further developments this quarter

GMOs

EFSA has provided guidance [54] on submitting an application (including renewals) for authorisation of genetically modified food and feed and genetically modified plants for food and feed uses including cultivation under Regulation (EC) No 1829/2003 in the European Union. The guidance describes the community procedures for processing such applications, and provides instructions to applicants on how to prepare and present. It is supplemented with nine appendices such as examples of data presentation and a checklist. It complements two recently updated guidance documents of the EFSA Panel on genetically modified organisms, (GMO Panel) the *Guidance for risk assessment of food and feed from genetically modified plants* and the *Guidance on the environmental risk assessment of genetically modified plants*.

On a request from the European Commission the (EFSA GMO Panel) updated its 2006 scientific opinion on Post-Market Environmental Monitoring (PMEM) of Genetically Modified Plants (GMPs). The draft updated opinion was launched for a one-month public consultation with 294 comments received from 26 interested parties, many requesting further guidance. [55]The revised scientific opinion repeals the former 2006 scientific opinion of the EFSA GMO Panel on PMEM of GMPs.[56]

EFSA also published opinions on herbicide tolerant GM soybean 356043 and insect resistant GM soybean MON 87701.[57]

---

[53] EFSA Panel on Biological Hazards (BIOHAZ); Scientific Opinion on assessment of epidemiological data in relation to the health risks resulting from the presence of parasites in wild caught fish from fishing grounds in the Baltic Sea. EFSA Journal 2011;9(7):2320. [40 pp.] doi:10.2903/j.efsa.2011.2320. Available at: http://www.efsa.europa.eu/en/efsajournal/pub/2320.htm accessed 30.11.2011

[54] EFSA guidance on the submission of applications for authorisation of genetically modified food and feed and genetically modified plants for food or feed uses under Regulation (EC) No 1829/2003EFSA Journal 2011;9(7):2311. [27 pp.] doi:10.2903/j.efsa.2011.2311 Available at http://www.efsa.europa.eu/en/efsajournal/pub/2311.htm accessed 22.11.11

[55] European Food Safety Authority; Outcome of the public consultation on the draft Scientific Opinion of the Scientific Panel on Genetically Modified Organisms (GMO) providing Guidance on Post-Market Environmental Monitoring (PMEM) of genetically modified plants. Supporting Publications 2011:EN-182. [11 pp.] Available at http://www.efsa.europa.eu/en/supporting/doc/182e.pdf Accessed 05.01.12

[56] EFSA Panel on GMO; Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011;9(8):2316. [40 pp.] doi:10.2903/j.efsa.2011.2316.
http://www.efsa.europa.eu/en/efsajournal/pub/2316.htm Accessed 05.01.12

[57] See Scientific opinion on herbicide tolerant GM soybean 356043 for food and feed uses, import and processing Scientific Opinion of the GMO Panel - Published: 26 July 2011 Scientific opinion on insect

In the Quarter the EFSA GMO Panel considered an application from Monsanto for renewal of the authorisation for continued marketing of existing cottonseed oil, food additives, feed materials and feed additives produced from MON 531 cotton. The Panel's opinion was that information available for cotton MON531 addressed questions raised by the MS and that cotton MON531, as described in this application, is as safe as its conventional counterpart and is unlikely to have adverse effects on human and animal health and the environment in the context of its intended uses.[58]

Also considered was a request from the European Commission, for the EFSA GMO Panel to complement its scientific opinion on insect resistant and herbicide tolerant genetically modified (GM) maize MON 89034 x 1507 x NK603 (application EFSA-GMO-NL-2009-65) issued in 2010, to cover all sub-combinations independently of their origin. The EFSA GMO Panel scientific opinion covered the safety assessment of maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny, for food and feed uses, import and processing under Regulation (EC) No 1829/2003. Each single event present in maize MON 89034 x 1507 x NK603 and two of the three possible sub-combinations, namely maize 1507 x NK603 (EFSA-GMO-UK-2004-05) and maize MON 89034 x NK603 (EFSA-GMO-NL-2007-38), were previously assessed by the EFSA GMO Panel. In view of the European Commission's request and, having considered all relevant available information on maize MON 89034 x 1507 x NK603 and on the single maize events, the EFSA GMO Panel considers it unlikely that the sub-combinations have an adverse effect on human and animal health and the environment in the context of their intended uses, which cover food and feed uses, import and processing. This conclusion was further supported by the previous assessments of maize 1507 x NK603 and maize MON 89034 x NK603. The EFSA GMO Panel concludes that the present statement can complement the scientific opinion on maize MON 89034 x 1507 x NK603 to cover all sub-combinations independently of their origin.[59]

Novel Foods

In the previous quarter chromium picolinate was approved as a novel food ingredient and in this quarter Commission Implementing Decision of 9 August 2011 authorised the placing on the market of fermented black bean extract as a novel food ingredient under Regulation (EC) No 258/97 (notified under document C(2011) 5645). This stemmed from an application made to the UK in 2008 by the company Cantox Health Sciences International on behalf of CBC Co. Ltd (Japan) to place fermented black bean extract on the market as a novel food ingredient for use in food supplements. Following a favourable EFSA opinion in April 2011, fermented black bean extract as specified in the Annex to the Decison may be placed on the market in the EU as a novel food ingredient in food supplements without prejudice to the specific provisions of Directive 2002/46/EC and Regulation (EC) No 1925/2006, with a maximum intake of 4.5g per day. The designation must be 'fermented black bean (Soya) extract' or 'fermented Soya extract'. Measurement issues that might arise include quantification of the product in supplements, a-glucosidase inhibitory activity and soy isoflavone both of which have limits prescribed in the decision specification.

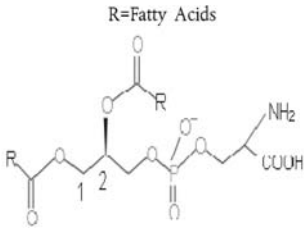
Similarly in 2009 Cantox Health Science International on behalf of the company Enzymotec Ltd made a request to the competent authorities of Finland to place Phosphatidylserine from soya phospholipids on the market as novel food ingredient.

---

resistant GM soybean MON 87701 for food and feed uses, import and processing Scientific Opinion of the GMO Panel - Published: 26 July 2011 - noted but not accessed

[58] EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on MON 531 cotton. EFSA Journal 2011;9(9):2373. [1-30] doi:10.2903/j.efsa.2011.2373. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2373.htm Accessed 06.01.12

[59] EFSA GMO Panel scientific opinion on maize MON 89034 x 1507 x NK603 (application EFSA-GMO-NL-2009-65), to cover all subcombinations independently of their origin. EFSA Journal 2011;9(9):2377. [8 pp.] doi:10.2903/j.efsa.2011.2377. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2377.htm Accessed 06.01.12



Phosphatidylserine

After clearance by the competent authority of Finland the compound was authorised as a novel food ingredient by Commission Implementing Decision of 19 August 2011 under Regulation (EC) No 258/97 (notified under document C(2011) 5897)[60] which refers to that fact that an objection on the maximum daily intake was taken into account (although quite how this was done is not apparent from the wording of the Decision).

In this quarter Commission Implementing Decision of 5 August 2011 authorising the placing on the market of phosphated maize starch as a novel food ingredient was published under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document C(2011) 5550). The product had already been cleared by the UK and EFSA as a novel food. The Decision allows phosphated distarch phosphate to be placed on the market in the EU as a novel food ingredient for use in baked bakery products, pasta, breakfast cereals and cereal bars to a maximum content of 15 %. The designation of phosphated distarch phosphate authorised by this Decision on the labelling of the foodstuff containing it shall be 'phosphated maize starch'.[61]

Health and Nutrition

Health Claims

The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), having by the end of June 2011 finalised the evaluation of all 'general function' health claims due to be adopted by that date continued to evaluate more specific claims. Some examples are included below to illustrate the approaches taken but readers are referred to the EFSA website for details of all opinions of health claim applications.

The quarter commenced with a report on 'toothkind' juice drinks. The Panel was requested to consider whether conclusions for the substantiation of the claimed beneficial effect, i.e. reduction of tooth demineralisation, can be drawn on the basis of studies which do not measure directly net demineralisation but measure the potential for demineralisation of enamel, e.g. reduced pH on dental plaque. The Panel considered that reduction of plaque pH immediately (within about 10 min) following a single consumption of a beverage is an appropriate measure of the potential of beverages for demineralisation of dental enamel. EFSA found that 'Toothkind' drinks have little or no potential for enamel demineralisation by

[60] Commission Implementing Decision of 19 August 2011 authorising the placing on the market of Phosphatidylserine from soya phospholipids as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document C(2011) 5897) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:215:0020:0022:EN:PDF

[61] Commission Implementing Decision of 5 August 2011 authorising the placing on the market of phosphated maize starch as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document C(2011) 5550): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:204:0023:0025:EN:PDF accessed 07.11.11

this process, while typical sugar-containing non-alcoholic beverages do have the potential for demineralisation of dental enamel. However, the beneficial effect (reducing net tooth demineralisation) of replacing typical sugar-containing non-alcoholic beverages with 'toothkind' juice drinks was only shown to occur at a frequency of consumption of typical sugar-containing non-alcoholic beverages of 7 times daily. On that basis the Panel considered that for people who consume conventional juice drinks or sugar-containing non alcoholic beverages and who are also frequent consumers of sugars and/or acids from other beverages and foods that can contribute to tooth demineralisation, a beneficial effect on maintaining tooth mineralisation may be expected by substitution of one or more servings of conventional juice drinks or sugar-containing non-alcoholic beverages with an equivalent number of servings of 'toothkind' juice drink. In the context of the claim, 'reduction of tooth demineralisation' has a similar meaning to 'maintenance of tooth mineralisation'.[62]

Given that a significant fraction of proposed health claims have not been supported by EFSA opinions it is instructive to consider the operation of mechanisms in place to allow the applicant company to challenge the EFSA NDA panel's views. Regulation (EC) No 1924/2006 does not envisage a consultation on the EFSA opinion. It does, however, allow for the applicant or indeed members of the public to make comments to the Commission relating to the EFSA opinion within 30 days from its publication. The Commission's services have established a practice for handling such comments and when the comments relate to the scientific assessment, they are transmitted to EFSA for consideration. The Commission and the Member States await the EFSA response to the comments before proceeding with the final discussion and the vote in the Standing Committee on the Food Chain and Animal Health on the draft measure authorising or rejecting a health claim.

In July EFSA reported on an example of this mechanism. In its opinion adopted on 28 January 2011, NDA concluded that a cause and effect relationship has not been established between the consumption of *Lactobacillus plantarum* TENSIA™ in the semi-hard Edam-type "heart cheese" of Harmony™ and maintenance of normal blood pressure. The applicant (Dairy Cooperative E-Piim), the University of Tartu and the Bio-Competence Centre of Healthy Dairy Products LCC commented on the NDA opinion rejecting the health claim. The comments received did not change the conclusions of the NDA Panel primarily because studies drawn to NDA's attention were considered to be effectively uncontrolled. This was both in their design (i.e., the order of administration of the test and control cheeses was not randomised, so that factors of, e.g., biological, technical or behavioural nature, other than the intervention and which could have an effect on blood pressure were not controlled for in the study design) and by the nature of the statistical analyses applied (i.e. the control period effectively was not taken into account in the data analysis for the test period). It was considered that no conclusion can be drawn from these studies for the scientific substantiation of the claimed effect. Taking into account that one study with an appropriate study design did not show an effect of the food constituent on blood pressure, EFSA considered that no conclusions could be drawn from mechanistic studies for the scientific substantiation of the claim since these could not predict an effect of the food constituent on blood pressure *in vivo* in humans.[63]

In view of our continuing interest in Aluminium consumption we record here an NDA scientific opinion on health claims in relation to silicon and protection against aluminium accumulation in the brain, cardiovascular health, forming a protective coat on the mucous membrane of the stomach, neutralisation of gastric acid, contribution to normal formation of collagen and

[62] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion - Statement on „toothkind" juice drinks. EFSA Journal 2011;9(7):2293. [7 pp.] doi:10.2903/j.efsa.2011.2293. available at http://www.efsa.europa.eu/en/efsajournal/doc/2293.pdf accessed 10.11.2011

[63] European Food Safety Authority; Response to comments on the Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on the scientific substantiation of health claims related to "Lactobacillus plantarum TENSIA™ in the semi-hard Edam-type "heart cheese" of Harmony™" and maintenance of normal blood pressure pursuant to Article 13(5) of Regulation (EC) No 1924/2006. Supporting Publications 2011:173. [5 pp.]. Available at http://www.efsa.europa.eu/en/supporting/doc/173e.pdf accessed 11.11.11

connective tissue, maintenance of normal bone, maintenance of normal joints, maintenance of normal appearance and elasticity of the skin, and contribution to normal formation of hair and nails. For a variety of reasons including, on the basis of data presented to it, the NDA concluded that a cause and effect relationship was not established between the consumption of silicon and the claimed health effects, and rejected the claims.[64]

Red yeast rice – monacolins

Red yeast rice is a traditional Chinese food product which is still a dietary staple in many Asian countries. Various red yeast rice preparations are available as food supplements. Depending on the *Monascus* strains used and the fermentation conditions, the products may contain polyketides called monacolins, which are secondary metabolites produced during fermentation. Monacolin K, in lactone (also known as lovastatin or mevinolin) and hydroxy acid forms, are the main monacolins in *Monascus purpureus*-fermented rice (75-90 % of total monacolin content). EFSA evaluated a proposed claim for monacolin K from red yeast rice and maintenance of normal blood LDL-cholesterol concentrations pursuant to Article 13(1) of Regulation (EC) No 1924/2006 in relation to "cholesterol" and "cholesterol management and heart health". It is interesting to note that whereas Monacolin K from *Monascus purpureus*-fermented rice is a well defined compound, which can be measured in foods by established methods, the Panel considered that red yeast rice is not sufficiently characterised in relation to the claimed effect. In weighing the evidence, the Panel took into account that two randomised controlled trials provided from which conclusions could be drawn for the scientific substantiation of the claim showed an effect of red yeast rice preparations providing a daily dose of about 10 mg monacolin K on LDL cholesterol concentrations in individuals with hypercholesterolaemia, that the effect of pure monacolin K on LDL cholesterol concentrations is well established and that the mechanism by which monacolin K can contribute to the claimed effect is well known. On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of monacolin K from red yeast rice and maintenance of normal blood LDL cholesterol concentrations. In order to obtain the claimed effect, 10 mg of monacolin K from fermented red yeast rice preparations should be consumed daily, according to the Panel. In relation to restrictions of use, the Panel refers to the Summary of Product Characteristics of lovastatin containing medicinal products available on the EU market.[65]

Food Supplements

See above under toxicology for a note on kava.

Glavonoid

The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) published an opinion on the safety of 'Glavonoid' as a food ingredient in the context of Regulation (EC) No 258/97. Glavonoid is an extract derived from the root or rootstock of Glycyrrhiza glabra L. by extraction with ethanol followed by further extraction with medium-chain triglycerides. The applicant intends to market Glavonoid as food supplements and as an ingredient for fruit juices, yoghurts and yoghurt drinks up to a dose of 300 mg per day to the general adult population. The Panel concluded that the novel food ingredient Glavonoid is safe for the general adult population up to 120 mg/day.

According to the report Glavonoid is a dark-brown coloured liquid, standardised to a content of approximately 3.0 % of the prenylated flavonoid glabridin, which is the most abundant constituent of the polyphenol fraction contained in the product and has a total fat content (ether extract and including polyphenolic type substances) of more than 99 % and the total

[64] EFSA Journal 2011;9(6):2259. [28 pp.]. doi:10.2903/j.efsa.2011.2259.Available at http://www.efsa.europa.eu/en/efsajournal/pub/2259.htm accessed 11.11.11

[65] EFSA Journal 2011;9(7):2304, available at: http://www.efsa.europa.eu/en/efsajournal/pub/2304.htm accessed 30.11.2011

content of medium chain triglycerides (MCT), free fatty acids, phospholipids and sterols was approximately 68 %. The applicant anticipated that the remaining constituents in the ether extract of Glavonoid, i.e. approximately 30 %, are hydrophobic polyphenolic-type substances. The applicant provided a HPLC chromatogram (UV detector at 282 nm) of an ethanolic extract of Glycyrrhiza glabra L. roots.Separation and refinement of the extract were performed with reverse-phase and normal-phase silica gel column chromatography and preparative HPLC with a reverse-phase column. All peaks, whose area was larger than 0.2 % of the total peak area, were further analysed by mass spectrometry and structures for 45 compounds were tentatively assigned. The most prominent peak corresponded to the prenylated flavonoid glabridin. Other prominent peaks were identified as the prenylated flavonoids glabrene, glabrol and 4'-O-methylglabridin. The 45 polyphenolic-type substances, for which structures were tentatively assigned, were classified as chalcone, isoflavan, isoflavene, 3-arylcoumarin, pterocarpan, 2-arylbenzofuran, flavone, isoflavone, flavanone and flavanol. In addition, comparisons of HPLC chromatograms (UV detector at 282 nm and 254 nm) of five batches of ethanolic extracts of Glycyrrhiza glabra L. roots showed that the patterns of peaks were qualitatively and quantitatively relatively consistent.[66]

Regulation

Official controls - products of non- animal origin

Commission Regulation (EC) No 669/2009 (see previous editions of this work) lays down rules concerning the increased level of official controls to be carried out on imports of feed and food of non- animal origin listed in an Annex (Annex I thereto 'the list'), at the points of entry into the EU. The list is reviewed on a regular basis, and at least quarterly, taking into account various given sources of information, e.g. RASFF. In the quarter the list was further amended by Regulation (EU) No 799/2011 of 9 August 2011 and republished in its entirety owing to the number of previous amendments. The parameters in question cover aflatoxins, pesticides, Aluminium in Chinese noodles, Cadmium, Lead, ochratoxin and Sudan dyes. Of these there are few analytical problems however the methods appropriate for Aluminium in noodles are under investigation by several bodies including the Government Chemist. [67]

Official controls - products of animal origin

Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption in particular, meat inspections and animal diseases. This was amended in the quarter by Regulation (EU) No 739/2011 of 27 July 2011.[68] Changes to animal disease classifications by the World Organisation for Animal Health (OIE) are reflected in the amendment mainly by reference to animal diseases covered by EU legislation in relation to ante- mortem or post-mortem inspection or any other inspection activity, unless reference is made to currently unknown diseases originating in third

[66] Scientific Opinion on the safety of „Glavonoid®", an extract derived from the roots or rootstock of Glycyrrhiza glabra L., as a Novel Food ingredient on request from the European Commission. EFSA Journal 2011;9(7):2287. [27 pp.]. doi:10.2903/j.efsa.2011.2287. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2287.htm accessed 22.11.11

[67] Commission Implementing Regulation (EU) No 799/2011 of 9 August 2011 amending Annex I to Commission Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:205:0015:0021:EN:PDF accessed 07.11.11

[68] Commission Implementing Regulation (EU) No 739/2011 of 27 July 2011 amending Annex I to Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of officials controls on products of animal origin intended for human consumption: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:196:0003:0005:EN:PDF

countries. The opportunity was also taken to allow an official veterinarian to impose industrial heat treatment, or other treatment to eliminate salmonella, to certain fresh poultry meat.

EFSA

EFSA Annual Report

The EFSA 2010 Annual Report was published in July 2011. In 2010, EFSA delivered 565 scientific outputs on a number of important issues including, amongst others, Q fever, influenza H1N1 and bisphenol A. In addition to providing robust scientific advice and risk assessment to European risk managers, EFSA took the opportunity in 2010 to reflect on its own structures and processes and also initiated a wide-ranging review to further strengthen its internal procedures regarding independence.[69]

Electronic transmission of results of analytical measurement

Compiling, checking and storing data from various MS is a major EFSA task. A project to implement and test an electronic system for the transmission of food contaminants and pesticide residues data to EFSA, according to EFSA standards was reported. The procedures and software tools developed under this project have been successfully tested and will be used in data transmission from Germany to EFSA in future.[70]

EU Almanac

In September 2011 BfR (Bundesinstitut für Risikobewertung, Federal Institute for Risk Assessment) published (in English) a useful and concise depiction of the Food and Feed Regulatory structures in 33 European countries and the European Community, the EU Food Safety Almanac. Each of the 33 country profiles contains a diagram that depicts the structure of governmental authorities and a detailed description of tasks and responsibilities of each institution. The Almanac explains which authorities are responsible for the assessment of plant protection products, health claims or zoonoses, which ministries in the Member States are responsible for the management in which areas, how risks are communicated and to what extent risk assessment and risk management are institutionally separated. Each country profile provides a three page overview of public authorities in the area of food and feed safety.[71]

FSA

The Agency in September published the Annual Report of the Chief Scientist, a review of its science and research during the past year. Highlights of the report include a review of efforts to reduce foodborne disease, developments in research on emerging risks and efforts to improve science governance to support the open, science- and evidence-based approach central to FSA's work.[72]

---

[69] http://www.efsa.europa.eu/en/corporate/pub/ar10.htm accessed 05.01.12

[70] Gunter Sommerfeld and Matthias Frost, 2011, Electronic Transmission of Chemical Occurrence Data, CFP/EFSA/DATEX/2009/01, Final technical report submitted to EFSA by German Federal Office of Consumer Protection and Food Safety (BVL). Available at http://www.efsa.europa.eu/en/supporting/pub/193e.htm Accessed 06.01.12

[71] EU Food Safety Almanac, 2011, 2nd updated and revised edition, Publisher: Federal Institute for Risk Assessment (BfR), Berlin, Germany (www.bfr.bund.de), Editors: Klaus Jürgen Henning, Dr. Brigitte Anna Graf, Susanne Kaus and PD Dr. Gaby-Fleur Böl. Availabel in English at http://www.bfr.bund.de/cm/364/eu-food-safety-almanac.pdf Accessed 06.01.12

[72] Food Standards Agency, 2011, Annual Report of the Chief Scientist, 2010-2011, available at http://www.food.gov.uk/news/newsarchive/2011/sep/csr2011 accessed 06.01.12

The Food and Drug Administration

Although it is not solely responsible for ensuring the safety of the nation's food supply, the U.S. Food and Drug Administration (FDA) oversees monitoring and intervention for 80 percent of the US food supply. Enhancing Food Safety: The Role of the Food and Drug Administration, a new book from the Institute of Medicine and the National Research Council, responds to a congressional request for recommendations on how to close gaps in FDA's food safety systems. Conclusions and recommendations include adopting a risk-based decision-making approach to food safety; creating a data surveillance and research infrastructure; integrating federal, state, and local government food safety programs; enhancing efficiency of inspections; and more.[73] An interesting aspect of FDA's work programme lies in its work with other government agencies and private sector organizations to help reduce the risk of tampering or other malicious, criminal, or terrorist actions on the food and cosmetic supply.[74]

Feeding Stuffs and Fertilisers

Undesirable Substances in Feed

Nitrite, Melamine, *Ambrosia* spp., Coccidiostats and Histomonostats

No further developments this quarter

Catalogue of feed materials

No further developments this quarter

Feed Additives

Commission Implementing Regulation (EU) No 868/2011 of 31 August 2011 concerning the authorisation of a preparation of Lactobacillus plantarum (DSM 21762) and of a preparation of Lactobacillus buchneri (DSM 22963) as feed additives for all animal species was made.[75]

[73] Enhancing Food Safety : The Role of the Food and Drug Administration, 2010, 588 pages, Institute of Medicine, Available http://www.nap.edu/catalog.php?record_id=12892

[74] FSA, Food Defense & Emergency Response, 2011, http://www.fda.gov/Food/FoodDefense/ucm2006914.htm Accessed 06.01.12

[75] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:226:0002:0004:EN:PDF