Food and Feed Law

Review of Changes in Food and Feed Legislation affecting the UK

April 2011 – June 2011

Statutory Analysis

Government Chemist Programme

LGC/R/2011/177

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1 Summary

Regulatory activity in the quarter April to June 2011 was somewhat down-regulated. However EFSA reported on three key horizon scanning activities that are of note, the Medical Information System, Emerging Risks Exchange Network and the Stakeholder Consultative Group on Emerging Risks. These may have some bearing on GC horizon scanning. The EFSA initiatives appear to be restricted access and thus are unlike the proposed GC Network Analysis Tool, which is destined for open use.

Contaminants usually feature highly in our quarterly summaries and work continues on cadmium in crab with Commission clarification that for crabs and crab-like crustaceans, the maximum cadmium limit applies to the appendages only. EFSA signalled a potential increase in the maximum limit (ML) for zearalenone in breakfast cereals from the current 50 µg/kg as an ML increase is unlikely to result in a chronic dietary exposure exceeding the TDI.

There were mixed results reported from 2007 – 2009 European monitoring for acrylamide with acrylamide decreasing in 'crackers', 'infant biscuits' and 'gingerbread' over the three years, increasing in 'crisp bread' and 'instant coffee', while showing no statistically significant change in six food groups. No European trend could be identified in eight other food groups.

EFSA also looked at polybrominated diphenyl ethers (PBDEs) in food, concluding that current dietary exposure in the EU does not raise a health concern possibly except for the BDE-99 congener.

In view of the current GC interest in aluminium we were pleased to see an EFSA report on a new study provided by industry that reports on the bioavailability of aluminium from several aluminium compounds in the rat. EFSA concluded that this study does not give reason to reconsider the previous safety evaluation of aluminium-based food additives authorised in the European Union performed by EFSA in 2008.

A report in Chemical and Engineering News, (American Chemical Society), highlighted claims that "caramel coloring" might contain the carcinogenic by-products 2-methylimidazole and 4-methylimidazole. This was strenuously denied by industry sources and is reported here for interest only. FDA commented it will carefully review the matter but assesses that risk, if any, from the by-products would be associated with long-term exposure. FDA has no reason to believe that there is any immediate or short-term danger presented by the substances in food.

Also of interest was the report that China banned the use of wheat flour whiteners, including benzoyl peroxide and calcium peroxide, in May 2011.

A study was noted by Swiss authorities on migration of mineral oils from recycled newspapers into foodstuffs packaged in recycled board and a German report detailed analyses of substances with hormone-like activity in natural mineral waters although additional research would be needed in order to assess a potential health risk.

Veterinary residues came under EFSA scrutiny in a report on residue monitoring in live animals and animal products in the Member States. Altogether, in 2009, there were 764,736 samples reported. The level of non-compliance was generally less than 1 % the exceptions being a relatively high proportion of non-compliant samples found for anticoccidials: 2.05 % in poultry, 1.19 % in eggs, 4.44 % in rabbits and for chemical elements (2.25 %) where cadmium, lead, and mercury were the most frequently reported elements. Not unexpectedly dyes were reported in aquaculture (1.6 %). Substances found were malachite green and leuco-malachite-green.

In April EFSA published several studies on irradiation of food. These were generally reassuring. The only new contrary evidence for the chemical safety of irradiated food was indicated in publications on leukoencephalomyelopathy in cats which have been fed mainly or exclusively with highly irradiated feed (>25 kGy).

In terms of microbiological risks it is estimated that there are approximately nine million cases of human campylobacteriosis per year in the EU27. Interestingly, in view of the import of large amounts of frozen chicken into the UK, it was reported that more than 90 % risk reduction can be obtained by freezing carcasses for 2-3 weeks.

The largest outbreak of haemolytic uremic syndrome (HUS) ever reported started in Germany in May 2011. Some 44 people died. The Strain STEC O104:H4 was isolated as the causative agent.

On 30 June 2011 the EFSA NDA panel finalised the evaluation of all 'general function' health claims due to be adopted by that date. With the publication of this fifth series of scientific opinions, EFSA added an additional 536 claims to the 2,187 claims published to date. A remaining group of 35 claims is due to be published in July 2011. The European Commission and Member States will consider EFSA's scientific advice in deciding on the possible authorisation of such claims for food products.

At the end of March 2011 and following consultation (to which the Government Chemist made a detailed response) the Food Standards Agency published its updated Strategy to 2015: Safer food for the nation. The Agencies core principles were extended to include enforcing food law fairly.

The Commission amended Annex I to Directive 2002/32/EC on maximum levels for nitrite, melamine, Ambrosia spp. and carry-over of certain coccidiostats and histomonostats.The reasons for some of these interventions are interesting. In the case of nitrite it was found that it appears that the method of analysis for the determination of nitrite in feed does not always provide reliable analytical results with regard to the products and by-products from sugar beet and sugarcane and from starch production. The products concerned were exempted for the time being from the maximum level for nitrite in feed materials, while nitrite levels in those products and appropriate methods of analysis are further examined.

Two minor items concerned allergy, there were reported allergic reactions caused by certain products containing acid-hydrolysed wheat protein, see page 7 and efforts to control the spread of *Ambrosia* spp which are of public health concern due to the allergenic properties of their pollen. Inhalation of the plant pollen may, amongst other conditions, cause rhino-conjunctivitis and asthma. There is also some evidence for allergenicity of *Ambrosia* spp. pollen in animals, see page 23.

2 Introduction

This report, covering the period April to June 2011, is the first 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. Its primary purpose is to track changes in UK food and agricultural legislation building to an annual overview. 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 completion of annual and quarterly reports in the series of reviews of changes in UK food and feed legislation and provide 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 April 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-

[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

Lex. Extensive use has been made of the explanatory notes that accompany each set of domestic regulations.

3 Acknowledgements

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

4 Cross-Cutting Issues

4.1 Radionuclide levels in food products from Japan

Following the accident at the Fukushima nuclear power station on 11 March 2011, the Commission was informed that radionuclide levels in certain food products originating in Japan such as milk and spinach exceeded the action levels in food applicable in Japan. Therefore 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. Commission Implementing Regulation (EU) No 506/2011 of 23 May 2011 amended Regulation (EU) No 297/2011 as the Commission had been informed of the finding of high levels of the radioactive caesium in green tea leaves, originating in the prefecture Kanagawa a prefecture is not previously listed among those where a pre-export test is required. Some other aspects of the original regulation were also clarified.[3]

4.2 Horizon Scanning

The following entries, used by EFSA in horizon scanning, the Medical Information System, Emerging Risks Exchange Network and the Stakeholder Consultative Group on Emerging Risks may have some bearing on GC horizon scanning. Note, unlike the proposed Network Analysis Tool, under GC capability building, which is destined for public use, these sources of information are restricted to EFSA, Commission and associated personnel.

4.2.1 Medical Information System (MedISys)

The Medical Information System (MedISys) is a fully automatic public health surveillance system to monitor reporting on human and animal infectious diseases, chemical, biological, radiological and nuclear (CBRN) threats (Linge et al., 2009), and food & feed contamination (Rortais et al., 2010). The system retrieves news articles from the internet, categorizes all incoming articles according to predefined multilingual categories, identifies entities such as organizations, persons and locations, extracts events, clusters news articles and calculates statistics to detect emerging threats. Users can screen the categorized articles and display world maps highlighting event locations together with statistics on the reporting of health threats, countries and combinations thereof. Articles can be further filtered by language, news source, and country. Within the Service-level agreement (SLA), EFSA and JRC have extended the threat detection system MedISys to food & feed hazards. The media coverage of MedISys has been extended by 300 sources. Over 200 filters for common food & feed hazards have been added covering additives and supplements, animal health, biological hazards, contaminants, feed, food contact material, GMO, nutrition and allergens, pesticides and plant health. Within these filters, areas of broader scope were covered (i.e. drivers of change which could have an indirect impact on the food chain). The multi-lingual filters have been tested and fine-tuned to reduce the volume of news articles per day to a manageable level; users can select official or general news sources. Deduplication is performed with the same algorithm used for Europe Media Monitor (EMM). The menu structure of the web site has been amended so that all filters are easily accessible via the web interface. EFSA has its

[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

own tab on the menu of the restricted MedISys site which allows all EFSA staff to screen news articles for the new filters. Press coverage on EFSA is available for press officers and senior management.

References:

Linge JP, Steinberger R, Weber TP, Yangarber R, van der Goot E, Al Khudhairy DH, Stilianakis NI, (2009). Internet surveillance systems for early alerting of health threats. Eurosurveillance 14(13).pii: 19162.

Rortais A, Belyaeva J, Gemo M, van der Goot E, Linge JP (2010). MedISys: An early-warning system for the detection of (re-)emerging food and feed-borne hazards. Food Research International 43, 1553–1556.

4.2.2 EFSA Emerging Risks Exchange Network

EFSA reported the activities of the EFSA Emerging Risks Exchange Network. The Network met for the first time in 2010. The initial activities of the Network were focused on scientific and generic issues of importance for the exchange of relevant information for the detection of medium- and long-term emerging risks. A number of emerging issues were presented, namely: reports of associations of pine nuts and a bitter metallic taste in certain food stuffs; the possibility that rapidly changing consumption patterns for energy drinks could lead to an increase in exposure levels to caffeine and other ingredients in children and young adults, and reported allergic reactions caused by certain products containing acid-hydrolysed wheat protein. A number of issues were raised by EREN including:

(i) the interest in sharing signals of emerging risks within the EREN structure; (ii) the need to discuss and establish a common lexicon of terms; Emrisk Network Report 2010 (iii) a general consensus that tools are required for filtering and communicating data from different data sources; (iv) the need for EFSA to establish a code of practice for the sharing and use of emerging risks information with and by Member States; (v) the recognition that communication on emerging risks is a sensitive issue with specific concerns that need to be properly considered and effectively delivered; (vi) an interest in encouraging the development of an European scientific journal devoted to the epidemiology, surveillance, prevention and control of food borne issues; (vii) the concern about the use of unauthorised ingredients in food supplements; and (viii) a widespread agreement about a need to address the lack of consumption data on energy drinks. The report concluded by observing that it is anticipated holding three network meetings in 2011. This should provide the opportunity to test the efficacy of using this structure to share data on and analyses of potential emerging risks.[4]

4.2.3 EFSA Stakeholder Consultative Group on Emerging Risks

EFSA has established the Stakeholder Consultative Group on Emerging Risks (StaCG-ER) in order to improve exchange of ideas and methods on the identification of emerging risks, but also for openness and transparency, information and data sharing, communication and dialogue on issues pertaining to emerging risk.

Members of StaCG-ER were selected by EFSA from nominations made through EFSA's Stakeholder Consultative Platform (SCP). The SCP is composed of EU-wide stakeholder organisations working in areas related to the food chain, and assists EFSA in the development of its overall relations and policy with stakeholders. The selection of members for StaCG-ER was based on the individual expertise of the nominees, ensuring a balanced representation of stakeholders (including food and feed producers, farmers, traders and consumers).

The group was asked to provide information related to emerging risks identification under three headings, namely (i) current methods and approaches (ii) data sources and tools and

[4] Annual report on the Emerging Risks Exchange Network 2010: EFSA, 2011, accessed 25 July 2011, http://www.efsa.europa.eu/en/supporting/pub/153e.htm

(iii) future approaches to be developed. In total, four meetings of the StaCG-ER were held in a period of eleven months, all meetings being chaired by EFSA staff.

The identification of emerging risks is an essential part of the daily activities in the food and feed sector organisations and is undertaken through regular monitoring of various data sources combined with information received through the organisations' networks. A common approach among stakeholders is the use of expert groups to discuss the relevance and importance of signals of potential emerging risks. There is an emphasis on the need for a multidisciplinary approach to be reflected in the choice of members of such groups.

Whilst data sources vary according to the scope of each organisation and therefore are sector specific, some general approaches can be highlighted. Expertise of individual scientists which are employees, members or collaborators of these organisations is a considerable pool of knowledge for the detection and prioritisation of emerging issues. Scientific literature, institutional reporting and the Rapid Alert System for Food and Feed (RASFF) are acknowledged as frequently used data sources.

Potential drivers of emerging risks are discussed in the report. Whilst drivers themselves are not specifically risks, they may, individually and/or in combination, affect the way that potential risks develop in the food and feed chain. Understanding the increasing complexity of how these drivers influence each other is a challenge in itself. These drivers are related to general themes of social/economic developments, changes in human lifestyle/diet, operation and functioning of the feed and food chain, technology/analytical developments and environmental/climate change.

Whereas each stakeholder/operator should be aware of the issues in their area, the EFSA group recognises that not all operators have the capacity to identify and interpret the impact of emerging issues/risks. In order to strengthen the capability to identify emerging risks of public health importance, a multidisciplinary and multi-stakeholder approach is essential for both vision and interpretation, as is a means for sharing information and accumulated knowledge. Therefore, the development of a common language with shared definitions, terminology and methodology is necessary.

Finally the report concluded that a system needs to be developed or deployed to assist in the interpretation and impact assessment of newly reported issues and signals of change which may be significant. It should include clear criteria and definitions for the interpretation of signals against the backdrop of the drivers identified, leading to a proportionate response as the issue matures. The report suggests such a model to frame and structure the above mentioned system, which should be further developed and elaborated in order to be explicit and operational.[5]

5 Food Safety

5.1 Regulated Contaminants in Food

5.1.1 Cadmium in Crab and other amendments of 1881/2006

Commission Regulation (EU) No 420/2011 of 29 April 2011[6] amended Regulation (EC) No 1881/2006 setting maximum levels[7] for certain contaminants in foodstuffs principally by clarifying limits for Cd in crab but also taking the opportunity to tidy up provisions of the Regulation. Regulation 1881/2006 applies cadmium limits to muscle meat from appendages (legs and claws) and abdomen but for crabs and crab-like crustaceans, the maximum level applies to the *appendages only*. This definition *excludes* other parts of crustaceans, such as

[5] Report on Stakeholders' activities in the area of emerging risks, accessed 25 July 2011, http://www.efsa.europa.eu/en/supporting/pub/170e.htm

[6] Commission Regulation (EU) No 420/2011 (accessed 25 July 2011) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:111:0003:0006:EN:PDF

[7] Commission information on cadmium regulation: http://ec.europa.eu/food/food/chemicalsafety/contaminants/cadmium_en.htm

the cephalothorax of crabs and inedible parts (shell, tail). The cephalothorax comprises the digestive organs (hepatopancreas) which are known to contain high levels of cadmium. In some Member States consumers may eat parts of the cephalothorax on a regular basis, thus consumer advice at a Member State level to limit consumption of these parts may be appropriate to reduce exposure to cadmium. An Information Note on this issue has been made available on the website of the Health and Consumers Directorate General of the European Commission.[8]

For consistency similar clarification was made on the maximum levels for other contaminants (lead, mercury, dioxins and PCBs and polycyclic aromatic hydrocarbons).

The default maximum levels for lead and cadmium in fruit and vegetables are not realistic for seaweed, which can naturally contain higher levels. Seaweed is therefore exempted from the default maximum levels for lead and cadmium in fruit and vegetables (points 3.1.10 and 3.2.15). More occurrence data needs to be collected to decide about the need for specific more realistic maximum levels for lead and cadmium in seaweed.

Bivalve molluscs such as green shell mussels and oysters can accumulate cadmium similarly to seaweed. Since green shell mussel powder and oyster powder, like dried seaweed, are sold as food supplements, the maximum level for cadmium in dried bivalve mollusc is made the same as that established for dried seaweed and products derived from seaweed.

The provisions for leafy brassica are aligned with those of other leaf vegetables and leafy brassica are excluded from the default maximum level for cadmium in 'vegetables and fruit' in point 3.2.15 and should be included in point 3.2.17.

Some inconsistencies are rectified between the names of the foodstuffs/product groups in Regulation (EC) No 1881/2006 and the names of the foodstuffs/product groups listed in Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides.

Finally the provisions on monitoring and reporting of ethylcarbamate, perfluoroalkylated substances and acrylamide are clarified.

5.1.2 Zearalenone

Zearalenone is a mycotoxin produced by several *Fusarium* species. It is commonly found in maize but can be found also in other crops such as wheat, barley, sorghum and rye. The European Commission asked the European Food Safety Authority to review the safety of zearalenone and the risk to consumers of a possible increase of the maximum level (ML) for zearalenone in breakfast cereals. A total of 13,075 analytical results obtained on food samples and 9,877 results on unprocessed grains sampled by 19 European countries in 2005 - 2010 were used in the evaluation. The highest concentrations of zearalenone were reported for wheat bran, corn and products thereof (e.g. corn flour, cornflakes). Grains and grain-based foods, in particular grains and grain milling products, bread and fine bakery wares, made the largest contribution to the estimated zearalenone exposures. Vegetable oils also made an important contribution to the zearalenone exposure. The critical effects of zearalenone result from its oestrogenic activity. Based on recent data in the most sensitive animal species, the pig, and taking into account comparisons between pigs and humans, the Panel on Contaminants in the Food Chain established a tolerable daily intake (TDI) for zearalenone of 0.25 µg/kg b.w. Estimates of chronic dietary exposure to zearalenone based on the available occurrence data are below or in the region of the TDI for all age groups and not a health concern. A potential increase in the maximum limit (ML) for zearalenone in breakfast cereals from 50 µg/kg to 75, 100, 125 or 150 µg/kg is unlikely to result in a chronic dietary exposure exceeding the TDI. In a worst case scenario it is possible that an individual could consume

[8] Commission note on cadmium in crab: http://ec.europa.eu/food/food/chemicalsafety/contaminants/information_note_cons_brown_crab_en.pdf

the same batch of breakfast cereal containing zearalenone at the ML every day for 2 to 4 weeks, in which case exposures may exceed the TDI.[9]

5.2 Other Contaminants

5.2.1 Acrylamide

EFSA published in April 2011 a report describing the results from the European acrylamide monitoring in the period from 2007 to 2009. Twenty three Member States and Norway submitted a total of 10366 acrylamide results for the three-year period. In 2009, mean acrylamide levels ranged from 37 µg/kg for 'soft bread' to 1504 µg/kg for 'substitute coffee', while the highest 95th percentile and maximum levels were reported for 'substitute coffee' at 3976 and 'potato crisps' at 4804 µg/kg, respectively. A mixed effect model was used to evaluate time trend changes in acrylamide levels in defined food groups. To detect clear statistical trends the number of years covered should be extended. However, based on the three years of information available it could be identified that acrylamide decreased in 'crackers', 'infant biscuits' and 'gingerbread' over the three years, increased in 'crisp bread' and 'instant coffee', while showing no statistically significant change in six food groups. No European trend could be identified in eight food groups, while there was insufficient information available for 'wafers', 'coffee not specified' and 'muesli and porridge' for the model fit. Mean acrylamide exposure in Europe was estimated to range between 0.31 and 1.1 µg/kg b.w. per day for adults (>18 years), between 0.43 and 1.4 µg/kg b.w. per day for adolescents (11-17 years), between 0.70 and 2.05 µg/kg b.w. per day for children (3-10 years) and between 1.2 and 2.4 µg/kg b.w. per day for toddlers (1-3 years). Major contributors to exposure for adults were 'fried potatoes' (including 'French fries'), 'coffee', and 'soft bread' whereas for adolescents and children they were 'fried potatoes', 'soft bread' and 'potato crisps' or 'biscuits'.[10]

5.2.2 Polybrominated diphenyl ethers (PBDEs) in food

EFSA was asked by the European Commission to deliver a scientific opinion on polybrominated diphenyl ethers (PBDEs) in food. PBDEs are additive flame retardants which are applied in plastics, textiles, electronic castings and circuitry. PBDEs are ubiquitously present in the environment and likewise in biota and in food and feed. Data from the analysis of 19 PBDE congeners in 3,971 food samples were provided to EFSA by 11 European countries. Eight congeners were considered by the Panel on Contaminants in the Food Chain (CONTAM Panel) to be of primary interest: BDE-28, -47, -99, -100, -153, -154, -183 and -209. The highest dietary exposure is to BDE-47 and -209. Toxicity studies were carried out with technical PBDE mixtures or individual congeners. Main targets were the liver, thyroid hormone homeostasis and the reproductive and nervous system. PBDEs cause DNA damage through the induction of reactive oxygen species. The Panel identified effects on neurodevelopment as the critical endpoint, and derived benchmark doses (BMDs) and their corresponding lower 95 % confidence limit for a benchmark response of 10 %, $BMDL_{10}$s, for a number of PBDE congeners: BDE-47, 309 µg/kg b.w.; BDE-99, 12 µg/kg b.w.; BDE 153, 83 µg/kg b.w.; BDE-209, 1,700 µg/kg b.w. Due to the limitations and uncertainties in the current database, the Panel concluded that it was inappropriate to use these BMDLs to establish health based guidance values, and instead used a margin of exposure (MOE) approach for the health risk assessment. Since elimination characteristics of PBDE congeners in animals and humans differ considerably, the Panel used the body burden as starting point for the MOE approach. The CONTAM Panel concluded that for BDE-47, -153 and -209 current

[9] Scientific Opinion on the risks for public health related to the presence of zearalenone in food EFSA Journal 2011;9(6):2197 [124 pp.]. doi:10.2903/j.efsa.2011.2197, accessed 25 July 2011, http://www.efsa.europa.eu/en/efsajournal/pub/2197.htm

[10] Results on acrylamide levels in food from monitoring years 2007-2009 and Exposure assessment, accessed 25 July 2011, http://www.efsa.europa.eu/en/efsajournal/pub/2133.htm

dietary exposure in the EU does not raise a health concern. For BDE-99 there is a potential health concern with respect to current dietary exposure.[11]

5.3 Food Allergens

5.3.1 Risk factors for food allergy

In a 70 page report the Dutch National Institute for Public Health and the Environment (RIVM) concluded that although the prevalence of food allergy appears to be increasing the reasons are not sufficiently well known. It is therefore not possible to formulate recommendations aimed at reducing the prevalence of food allergy. The increase cannot be explained by genetic changes and may be explained by alterations in exposure to external factors, such as changes in diet or lifestyle. The prevalence of food allergy varies from 2 % to 6 % in children and from 2 % to 3 % in adults. In this literature study, RIVM looked at the impact of microbes, environmental toxicants, diet and lifestyle on the development of food allergy. The effects of the majority of these external factors on food allergy could not be determined because there were either too few studies or the results of different studies were conflicting. There is limited evidence that the consumption of fish oil supplements during pregnancy reduces the risk of egg allergy, but these findings need to be confirmed in larger clinical trials. There are also indications that the delayed introduction of food allergens in the diet of infants is a risk factor; a number of clinical studies are currently investigating this hypothesis.[12]

5.4 Food Additives

5.4.1 Lycopene

The Food Additives (Amendment) (No. 2) Regulations (Northern Ireland) 2011 were made. These Regulations implement 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) ("the amending Directive"). The amending Directive 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.

These Regulations implement the amending Directive by making an amendment to regulation 2 of the Food Additives Regulations (Northern Ireland) 2009 (S.R. 2009 No. 416) so that the definition of Directive 08/128 in those regulations includes reference to the amending Directive. The permission to use the two new sources of lycopene (synthetic lycopene and lycopene from Blakeslea trispora) is brought into operation earlier than the revision of existing purity criteria for lycopene from red tomatoes.[13] Similar legislation was made in Wales.[14]

5.4.2 Aluminium in Food

In view of the current GC interest in aluminium we were pleased to see an EFSA report on a new study provided by industry that reports on the bioavailability of aluminium from several aluminium compounds in the rat. EFSA was asked whether the scientific data provided by the study could trigger the revision of the safety evaluation performed by EFSA in 2008, for the

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[11] Scientific Opinion on Polybrominated Diphenyl Ethers (PBDEs) in Food

EFSA Journal 2011;9(5):2156 [274 pp.]. doi:10.2903/j.efsa.2011.2156 accessed 25 July 2011,

http://www.efsa.europa.eu/en/efsajournal/pub/2156.htm

[12] J. Ezendam and H. van Loveren, 2010, Risk factors for food allergy, RIVM Report 340007001/2010 http://www.rivm.nl/bibliotheek/rapporten/340007001.pdf

[13] The Food Additives (Amendment) (No. 2) Regulations (Northern Ireland) 2011
http://www.legislation.gov.uk/nisr/2011/217/contents/made

[14] The Food Additives (Wales) (Amendment) (No. 2) Regulations 2011
http://www.legislation.gov.uk/wsi/2011/1450/contents/made

different aluminium based food additives investigated in this report (in particular SALP acidic, also known as sodium aluminium phosphate, acidic form or E 541). In the new study, the oral bioavailability of aluminium was determined as the ratio of the fraction of radioactivity left in the carcass seven days after oral administration of the ^{26}Al-labelled compound of interest over the fraction of radioactivity left in the carcass seven days after intravenous administration of ^{26}Al-labelled aluminium citrate using accelerator mass spectrometry (AMS). The results from the study show that the oral bioavailability of aluminium from twelve different aluminium-containing compounds, including the food additives aluminium sulphate, Allura Red AC aluminium lake (FD&C red 40 aluminium lake) and sodium aluminium silicate, ranges from 0.02 to 0.21 %, and therefore falls within the overall 10-fold range of previously reported oral bioavailability values for aluminium from aluminium containing compounds. In the case of the two sodium aluminium phosphates, SALP acidic and SALP basic (KASAL), and aluminium metal, the measurements were below the limit of detection by AMS. In conclusion, the new study does not provide any additional information on the bioavailability of aluminium from aluminium-containing compounds that could modify the conclusions reached in 2008 by the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials. Therefore, EFSA concluded that this study does not give reason to reconsider the previous safety evaluation of aluminium-based food additives authorised in the European Union performed by EFSA in 2008.[15]

5.4.3 Caramel Colouring

In March 2011 Chemical and Engineering News, American Chemical Society, reported that the American Center for Science in the Public Interest (CSPI) made a claim that "caramel coloring" used in colas and other dark-colored soft drinks contains the carcinogenic by-products 2-methylimidazole and 4-methylimidazole. This was strenuously denied by Coca Cola, which issued a statement to the effect that the caramel they use does not contain 2-methylimidazole and that 4-methylimidazole is found in trace amounts in a wide variety of foods and beverages. FDA commented it will carefully review the matter but assesses that risk, if any, from the by-products would be associated with long-term exposure. FDA has no reason to believe that there is any immediate or short-term danger presented by the substances in food.[16, 17, 18]

5.4.4 Ban of whitening agents for flour in China

The RSC house journal 'Chemistry World' reported that China will ban the use of wheat flour whiteners, including benzoyl peroxide and calcium peroxide, in May 2011. On 1 March, the Chinese Ministry of Health, together with six other ministries, released a notice to withdraw food additive licenses for benzoyl peroxide and calcium peroxide and ban their production and application as food additives. In China, the legal level of benzoyl peroxide or calcium peroxide as additives is no more than 60 mg/kg, which is much lower than international levels - for example in Canada the legal level is 150 mg/kg. [19]

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[15] Statement of EFSA on the Evaluation of a new study related to the bioavailability of aluminium in food EFSA Journal 2011;9(5):2157 [16 pp.]. doi:10.2903/j.efsa.2011.2157, accessed 25 July 2011, http://www.efsa.europa.eu/en/efsajournal/pub/2157.htm

16 Chemical and Engineering News, American Chemical Society http://cenblog.org/newscripts/2011/03/dark-colored-sodas-may-have-toxic-backwash-or-not/#more-8384

[17] Joon-Kwan Moon, Takayuki Shibamoto, 2011, Formation of Carcinogenic 4(5)-Methylimidazole in Maillard Reaction Systems, Journal of Agricultural and Food Chemistry, 59 (2), 615-618

[18] http://ntp.niehs.nih.gov/files/535_Web_Final.pdf and http://ntp.niehs.nih.gov/files/516final_web.pdf

[19] RSC Chemistry World, (accessed 25 July 2011) http://www.rsc.org/chemistryworld/News/2011/March/14031101.asp

5.5 Food Contact Materials

5.5.1 Migration of mineral oils from recycled newspapers

The BBC reported a study by Dr Koni Grob of the government food safety laboratory of the Canton of Zurich that found migration of mineral oils from recycled newspapers into foodstuffs packaged in recycled board. [20]

5.6 Natural Mineral and other Bottled Waters

A BfR (Bundesinstitut für Risikobewertung) report detailed analyses of substances with hormone-like activity in natural mineral waters. Oestrogen-like activities were not detected however a number of substances were identified for which no data on hormone-like activity is available yet. BfR concluded that mineral water should not exhibit hormone-like activity but that additional research would be needed in order to assess a potential health risk.[21]

5.7 Pesticides

EFSA has prepared a standard data model for the transmission of chemical occurrence data and pesticide residues. This model is referred to as the "Standard Model" (SM) or the "Standard Sample Description" (SSD). The aim of the present project was to collect and transform data from the Danish national data repositories for chemical contaminants and pesticides and in coding these according to the SM and to facilitate the continued use of the SM in answering future EFSA data calls in these areas. Procedures and Excel mapping tables were developed to handle the data transformation. The main challenges were mapping existing data to the SM, synthesising necessary information missing in the national repository, and dealing with the complexity of pesticide substance reporting.[22]

Commission Regulation (EU) No 310/2011 of 28 March 2011 amended Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aldicarb, bromopropylate, chlorfenvinphos, endosulfan, EPTC, ethion, fenthion, fomesafen, methabenzthiazuron, methidathion, simazine, tetradifon and triforine in or on certain products.[23]

Commission Regulation (EU) No 460/2011 of 12 May 2011 amended Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards the maximum residue level for chlorantraniliprole (DPX E-2Y45) in or on carrots.[24]

Commission Regulation (EU) No 520/2011 of 25 May 2011 amended Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benalaxyl, boscalid, buprofezin, carbofuran, carbosulfan, cypermethrin, fluopicolide, hexythiazox, indoxacarb, metaflumizone, methoxyfenozide, paraquat, prochloraz, spirodiclofen, prothioconazole and zoxamide in or on certain products.[25]

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[20] BBC, 2011, http://www.bbc.co.uk/news/uk-12663183 (accessed 25 July 2011)

[21] BfR, 2011, http://www.bfr.bund.de/cm/245/bfr_assesses_analyses_of_substances_with_hormone_like_activity_in_natural_mineral_waters.pdf (accessed 25 July 2011)

22 Implementation of Electronic Transmission of Chemical Occurrence Data CFP/EFSA/DATEX/2009/01) in Denmark (accessed 25 July 2011)
http://www.efsa.europa.eu/en/supporting/pub/152e.htm see also
http://www.efsa.europa.eu/en/supporting/doc/154e.pdf

[23] Commission Regulation (EU) No 310/2011
http://eur-ex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:100:0026:0027:EN:PDF

[24] Commission Regulation (EU) No 460/2011
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:124:0023:0040:EN:PDF

[25] Commission Regulation (EU) No 520/2011
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:140:0002:0047:EN:PDF

Commission Regulation (EU) No 524/2011 of 26 May 2011 amended Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for biphenyl, deltamethrin, ethofumesate, isopyrazam, propiconazole, pymetrozine, pyrimethanil and tebuconazole in or on certain products.[26]

Commission Regulation (EU) No 559/2011 of 7 June 2011 amended Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for captan, carbendazim, cyromazine, ethephon, fenamiphos, thiophanate-methyl, triasulfuron and triticonazole in or on certain products.[27]

5.8 Veterinary Residues

Commission Regulation (EU) No 363/2011 of 13 April 2011 amended the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification setting a maximum residue limit for isoeugenol in fin fish of 6000 µg/kg on muscle and skin in natural proportions. Isoeugenol is classified as an agent acting on the nervous system/central nervous system.[28]

5.9 Residue Monitoring Results 2009

Pursuant to article 31 of Regulation EC 178/2002[1], the European Commission asked EFSA to analyse the results of residue monitoring in live animals and animal products in the Member States. Altogether, in 2009, there were 764,736 samples reported. A total of 484,087 samples (445,968 targeted samples, 38,119 suspect samples) were reported under the Council Directive 96/23/EC. Additionally, one Member State reported 280,649 samples for inhibitor tests which were not included in the overall assessment.

The minimum requirements for sampling frequency laid down in Council Directive 96/23/EC and in Commission Decision 97/747/EC have been fulfilled in 2009 for the EU overall, and by the vast majority of the individual Member States.

From the total of collected targeted samples, 40.9 % were analysed for substances having anabolic effect and prohibited substances (group A) and 63.1 % for veterinary drugs and contaminants (group B). There were 1,406 non-compliant samples (0.32 %) (1,493 non-compliant results) out of the 445,968 targeted samples. This situation was similar to the one in 2008 when 0.34 % of the targeted samples were non-compliant. The percentage of non-compliant samples calculated from the total number of samples analysed for substances in that category was: 0.18 % for substances having anabolic effect and prohibited substances (A), 0.21 % for antibacterials (B1), 0.30 % for “other veterinary drugs” (B2), and 1.08 % for “other substances and environmental contaminants” (B3).

Of all the targeted samples analysed for the category “hormones” in all animal/product categories, 0.26 % were non-compliant. As in 2008, there were no non-compliant samples for stilbenes and derivatives (A1). For antithyroid agents (A2), there were 0.46 % non-compliant samples, all for thiouracil, but most likely caused by feeding cruciferous plants. In the group of steroids (A3), which includes some results on corticosteroids, there have been 0.39 % non-compliant samples in all animal and product categories. The non-compliant samples were found in bovines (0.34 %), pigs (0.30 %), sheep and goats (3.65 %), horses (1.27 %), poultry (0.05 %), and aquaculture (0.46 %). The most frequent identified anabolic steroids were alpha-boldenone (n = 65), nandrolone (n = 64), and epinandrolone (n = 17). However, several Member States claimed that residues of boldenone-alpha and epinandrolone (19-norepitestosterone) were more likely of endogenous nature. Non compliant samples for corticosteroids were reported in group A3 (n = 27) and in group B2f (n = 27). The majority of incidences of non-compliance for corticosteroids were reported in bovines (n = 48).

26 Commission Regulation (EU) No 524/2011
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:142:0001:0056:EN:PDF

27 Commission Regulation (EU) No 559/2011
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:152:0001:0021:EN:PDF

28 Commission Regulation (EU) No 363/2011 (accessed 24 July 2011)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:100:0028:0029:EN:PDF

Substances identified were dexamethasone (n = 43), prednisolone (n = 16), and prednisone (n = 5). In the group of resorcylic acid lactones (A4), 0.17 % of the samples were non-compliant for zearanol and taleranol. For beta-agonists (A5), only two non-compliant samples were detected in 2009 (0.01 %). For prohibited substances (A6), 0.07 % of the samples were found to be non-compliant. Substances identified were chloramphenicol (n = 25), nitrofurans (n = 25) and nitroimidazoles (n = 9).

For antibacterials (B1), 0.21 % of the samples analysed under Directive 96/23 were non-compliant. Additionally, Germany reported non-compliant results from applying inhibitor tests. The highest frequencies of non-compliant samples for antibacterials were found in honey (0.98 %), rabbit meat (0.63 %), and aquaculture (0.48 %).

There were 0.26 % non-compliant samples for substances in the category “other veterinary drugs” (B2). A relatively high proportion of non-compliant samples was found for anticoccidials (B2b): 2.05 % in poultry, 1.19 % in eggs, 4.44 % in rabbits, and 0.54 % in farmed game. Non-compliances for anthelmintics (B2a) were reported in bovines (0.14 %), pigs (0.1 %), sheep and goats (0.28 %), aquaculture (0.39 %), and milk (0.3 %). For carbamates and pyrethroids (B2c), there was only one non-compliant sample in pigs, and one in wild game. No non-compliant sample was reported for sedatives (B2d). For non-steroidal anti-inflammatory drugs (B2e) there were non-compliant samples in bovines (0.13 %), sheep and goats (0.2 %), horses (0.6 %), poultry (0.46 %), milk (0.03 %), and rabbits (1.39 %). Non-compliant samples for “other pharmacologically active substances” (B2f) were reported in bovines (0.37 %), poultry (0.2 %), and pigs (0.09 %).

There were 1.08 % non-compliant samples in the group of “other substances and environmental contaminants (B3)”. The highest percentage of non-compliant samples in almost all species was found for chemical elements (B3c) (2.25 %). Cadmium, lead, and mercury were the most frequently reported elements. Instances of non-compliance for organochlorine compounds (B3a) and organophosphorus compounds (B3b) were much lower: 0.19 % and 0.04 %, respectively. For mycotoxins (B3d), nine non-compliant samples for ochratoxin A in pigs, one for aflatoxin B1 in sheep and goats, and five for aflatoxin M1 in milk were reported. Dyes (B3e) were reported in aquaculture (1.6 %). Substances found were malachite green and leuco-malachite-green.

The residue situation in 2009 was similar to the two previous years for all substance groups. However, because the sampling plan and the spectrum of analysed substances were not necessarily the same over the three years, such comparisons should be regarded as having a high degree of uncertainty.[29]

5.10 Nanomaterials

The European Food Safety Authority has developed a practical approach for assessing potential risks arising from applications of nanoscience and nanotechnologies in the food and feed chain. Guidance is provided on: (i) the physico-chemical characterisation requirements of engineered nanomaterials used e.g. as food additives, enzymes, flavourings, food contact materials, novel foods, feed additives and pesticides and; (ii) testing approaches to identify and characterise hazards arising from the nanoproperties which, in general, should include information from *in vitro* genotoxicity, absorption, distribution, metabolism and excretion and repeated-dose 90-day oral toxicity studies in rodents. The guidance allows for reduced information to be provided when no exposure to the engineered nanomaterial is verified by data indicating no migration from food contact materials or when complete degradation/dissolution is demonstrated with no absorption of engineered nanomaterials as such. The guidance indicates uncertainties that should be considered to perform a risk

[29] Report for 2009 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products, accessed 25 July 2011, http://www.efsa.europa.eu/en/supporting/pub/158e.htm

assessment. As this sector is under fast development, this guidance document will be revised as appropriate.[30]

Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain, EFSA Journal 2011;9(5):2140 [36 pp.]. doi:10.2903/j.efsa.2011.2140, http://www.efsa.europa.eu/en/efsajournal/pub/2140.htm

5.11 Food Hygiene

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

Strain STEC O104:H4 was isolated as the causative agent for the largest outbreak of haemolytic uremic syndrome (HUS) ever reported, which started in Germany in May 2011 and includes several cases from other EU and non-EU countries linked to the outbreak. Some 44 people died. This report aims to give a short summary of reported Shiga toxin/verotoxin-producing *Escherichia coli* (STEC/VTEC) prevalence and incidence in humans, food and animals. The report focuses on cases reported in EU/EEA countries through the existing surveillance and monitoring systems in the European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA) and the comparison of characteristics of strains from earlier reported isolates/cases with the German outbreak strain.[31] This was followed by urgent advice on the public health risk of Shiga-toxin producing Escherichia coli in fresh vegetables.[32]

5.12 *Campylobacter* in broiler meat production

It is estimated that there are approximately nine million cases of human campylobacteriosis per year in the 27 member states of the European Union. The disease burden of campylobacteriosis and its sequelae is 0.35 million disability-adjusted life years (DALYs) per year and total annual costs are €2.4 billion. Broiler meat may account for 20 % to 30 % of these, while 50 % to 80 % may be attributed to the chicken reservoir as a whole (broilers as well as laying hens). The public health benefits of controlling Campylobacter in primary broiler production are expected to be greater than control later in the chain as the bacteria may also spread from farms to humans by other pathways than broiler meat. Strict implementation of biosecurity in primary production and GMP/HACCP during slaughter may reduce colonization of broilers with Campylobacter, and contamination of carcasses. The effects cannot be quantified because they depend on many interrelated local factors. In addition, the use of fly screens, restriction of slaughter age, or discontinued thinning may further reduce consumer risks but have not yet been tested widely. After slaughter, a 100 % risk reduction can be reached by irradiation or cooking of broiler meat on an industrial scale. More than 90 % risk reduction can be obtained by freezing carcasses for 2-3 weeks. A 50-90 % risk reduction can be achieved by freezing for 2-3 days, hot water or chemical carcass decontamination. Achieving a target of 25 % or 5 % BFP in all other MS is estimated to result in 50 % and 90 % reduction of public health risk, respectively. A public health risk reduction > 50 % or > 90 % could be achieved if all batches would comply with microbiological criteria with a critical limit of 1000 or 500 CFU/gram of neck and breast skin, respectively, while 15% and 45% of all tested batches would not comply with these criteria.[33]

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[30] Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain, EFSA Journal 2011;9(5):2140 [36 pp.]. doi:10.2903/j.efsa.2011.2140, http://www.efsa.europa.eu/en/efsajournal/pub/2140.htm

[31] Joint EFSA/ECDC technical report: Shiga toxin/verotoxin-producing Escherichia coli in humans, food and animals in the EU/EEA, with special reference to the German outbreak strain STEC O104, accessed 25 July 2011, http://www.efsa.europa.eu/en/supporting/pub/166e.htm

[32] Urgent advice on the public health risk of Shiga-toxin producing Escherichia coli in fresh vegetables, EFSA Journal 2011;9(6):2274 [50 pp.]. doi:10.2903/j.efsa.2011.2274, accessed 25 July 20111, http://www.efsa.europa.eu/en/efsajournal/pub/2274.htm

[33] Scientific Opinion on Campylobacter in broiler meat production: control options and performance objectives and/or targets at different stages of the food chain EFSA Journal 2011;9(4):2105 [141 pp.]. doi:10.2903/j.efsa.2011.2105

6 Consumer Choice and Prevention of Fraud

6.1 Composition and Labelling

6.1.1 Fruit Juices and Fruit Nectars

The Fruit Juices and Fruit Nectars (England) (Amendment) Regulations 2011 No. 1135 were made, coming into force 16 May 2011 and amending the Fruit Juices and Fruit Nectars (England) Regulations 2003. It is interesting to note that the amending regulations are now made by Defra rather than FSA following the changes in machinery of government noted in previous reports. The Regulations, which apply in relation to England only, transpose Commission Directive 2009/106/EC amending Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption (OJ No. L 212, 15.8.2009, p. 42). The main effect is to introduce minimum Brix levels for fruit juices from concentrate. Other minor changes are made and the Regulations also require the Defra Secretary of State to review the operation and effect of the 2003 Regulations and publish a report within five years beginning on 16 May 2011 and within every five years after that. Following a review it will fall to the Secretary of State to consider whether the 2003 Regulations should remain as they are, or be revoked or be amended.[34]

6.1.2 Fruit juice authenticity

Test for signature organic acids such as tartaric acid and malic and quinic acids (from apple) by routine LC-UV is said to often have difficulty detecting low levels of the acids and with reproducibility. As a result, there is confusion over whether pure pomegranate juice contains tartaric acid, making it difficult to determine if some brands of pomegranate juice are unscrupulously topped off with grape juice.

The Grocery Manufacturers Association, a trade group, developed a liquid chromatography-mass spectrometry approach that is highly sensitive and unequivocal in identifying the organic acids.

With their method, the researchers confirmed that pomegranate juice does contain tartaric acid but at low levels: between 1 and 5 mg/L. Pomegranate juice adulterated by grape juice, by contrast, contains more than 50 mg/L of tartaric acid. [35]

6.1.3 Organic Food

Commission Implementing Regulation (EU) No 426/2011 of 2 May 2011 amended Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control.[36]

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http://www.efsa.europa.eu/en/efsajournal/pub/2105.htm accessed 25 July 2011; see also A quantitative microbiological risk assessment of Campylobacter in the broiler meat chain: http://www.efsa.europa.eu/en/supporting/pub/132e.htm

[34] The Fruit Juices and Fruit Nectars (England) (Amendment) Regulations 2011 (accessed 25 July 2011) http://www.legislation.gov.uk/uksi/2011/1135/made/data.pdf

[35] Ehling and Cole, Analysis of Organic Acids in Fruit Juices by Liquid Chromatography−Mass Spectrometry: An Enhanced Tool for Authenticity Testing J. Agric. Food Chem., DOI: 10.1021/jf104527e. Abstract at (accessed 25 July 2011) http://pubs.acs.org/doi/abs/10.1021/jf104527e original reference Chemical and Engineering News, American Chemical Society.

36 EU Commission, 2011, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:113:0001:0002:EN:PDF

6.2 Novel Foods

Commission Decision of 27 May 2011 authorised the placing on the market of Chromium Picolinate as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document C(2011) 3586).[37]

6.3 Food Irradiation

In April EFSA published several studies on irradiation of food. These were generally reassuring. The only new contrary evidence for the chemical safety of irradiated food was indicated in publications on leukoencephalomyelopathy in cats which have been fed mainly or exclusively with highly irradiated feed (>25 kGy). This finding has only been reported with cats. In one report, dogs consumed the same pet food and did not show the disease. Several hypotheses have been put forward in the literature (e.g. specific sensitivity of cats to deficiency in vitamins which may be caused by irradiation, peroxides generated by irradiation). However a clear mechanistic explanation in terms of risk assessment has not been established. In absence of this understanding, the relevance for humans cannot be ruled out. Considering that only a very limited quantity of food is irradiated in Europe currently, the Panel is of the view that there is not an immediate cause for concern. However, the relevance of the cats' studies for human health should be clarified.[38]

6.4 GMOs

The Annual report the EFSA Scientific Network for Risk Assessment of GMOs was published in April 2011.[39] This was followed by updated guidance for the risk assessment of food and feed containing, consisting or produced from genetically modified (GM) plants, submitted within the framework of Regulation (EC) No 1829/2003 on GM food and feed. The risk assessment strategy for GM plants and derived food and feed proposed seeks to deploy appropriate approaches to compare GM plants and derived food and feed with their respective comparators. The underlying assumption of this comparative approach is that traditionally cultivated crops have gained a history of safe use for consumers and/or domesticated animals. The document provides guidance on how to perform the comparative analysis of the relevant characteristics of the GM plant. The document addresses the details of the different components of the risk assessment: the molecular characterisation, which provides information on the structure and expression of the insert(s) and on the stability of the intended trait(s); the toxicological assessment, which addresses the impact of biologically relevant change(s) in the GM plant and/or derived food and feed resulting from the genetic modification; the assessment of potential allergenicity, of the novel protein(s) as well as of the whole food derived from the GM plant; the nutritional assessment to evaluate whether food and feed derived from a GM plant is not nutritionally disadvantageous to humans and/or animals. In addition every section of the document addresses specifically the requirements for GM plants containing a combination of transformation events, providing guidance on how to establish that the combination is stable and that no interactions occurs between the events that may raise safety concerns. The document does not cover the environmental risk assessment of GM plants which is addressed in a stand-alone environmental risk assessment (ERA) guidance document developed by the EFSA GMO Panel.[40]

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[37] Commission Decision of 27 May 2011 on Chromium Picolinate
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:143:0036:0037:EN:PDF

[38] Scientific Opinion of the CEF Panel - Published: 6 April 2011, Chemical Safety of Irradiation ; EFSA Statement on the safety of Irradiation of Food and Scientific Opinion of the BIOHAZ Panel - Published: 6 April 2011 Efficacy and microbiological safety of irradiation of food

[39] Annual report the EFSA Scientific Network for Risk Assessment of GMOs:
http://www.efsa.europa.eu/en/supporting/pub/143e.htm

[40] Guidance for risk assessment of food and feed from genetically modified plants EFSA Journal 2011; 9(5): 2150 [37 pp.]. doi:10.2903/j.efsa.2011.2150 - accessed 25 July 2011,
http://www.efsa.europa.eu/en/efsajournal/pub/2150.htm

6.4.1 Genetically Modified Cotton

COMMISSION DECISION of 17 June 2011 authorised the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB614 (BCS-GHØØ2-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.[41]

7 Health and Nutrition

By early April 2011 EFSA's NDA Panel had published the outcome of the evaluations of a fourth series of 'general function' health claims proposed for use on food products. The 442 claims assessed relate to health relationships in such areas as: protection against oxidative damage to body cells, contribution to either cognitive or bowel function; and maintenance of normal blood cholesterol levels. These opinions will help inform future decisions of the European Commission and EU Member States which are responsible for the authorisation of the claims. Claims evaluated with a favourable outcome include the relation between: walnuts and improved function of blood vessels; the antioxidant effects of polyphenols found in olive oil on LDL cholesterol; and the relation between caffeine and alertness and caffeine and increased physical endurance. The Panel also concluded that a number of claims based on the replacement of certain nutrients were supported by sufficient scientific evidence including: the replacement of digestible starch by resistant starch to lower the increase of blood glucose levels after meals; the replacement of saturated fatty acids with mono- and polyunsaturated fatty acids to maintain normal blood cholesterol levels; as well as the role of a range of sugar replacers (e.g. xylitol or sorbitol) in maintaining tooth mineralisation or lowering the increase of blood glucose levels after meals.

As for previous evaluations, many of the unfavourable opinions in this series were linked to the poor quality of the information provided to EFSA. Information gaps included, for instance: the inability to identify the specific substance on which the claim was based; the lack of evidence that the claimed effect is indeed beneficial to the maintenance or improvement of body functions; or the lack of precision regarding the health claim being made. In addition, some claims were outside the scope of the current legal framework.

On 30 June 2011 the NDA panel finalised the evaluation of all 'general function' health claims due to be adopted by that date. With the publication of this fifth series of scientific opinions, EFSA added an additional 536 claims to the 2,187 claims published to date. A remaining group of 35 claims is due to be published in July 2011. The European Commission and Member States will then consider EFSA's scientific advice in deciding on the possible authorisation of such claims for food products.

Of the 536 claims evaluated in this latest series, favourable outcomes include the relation between specific dietary fibres and blood cholesterol; cereal fibre and bowel function; carbohydrate-electrolyte drinks and endurance performance; low sodium and blood pressure; dietary fibre and reduced increase in blood glucose after meals; melatonin and sleep onset and very low calorie diet in relation of body weight.

Other claims in this series received unfavourable evaluations because NDA Panel experts concluded that they were not sufficiently specific, such as claims on "women's health" or "mental energy", or that they referred to food categories which were considered to be too broad, such as "fruits and vegetables", "dairy products", to be linked to specific effects. Other claims were unfavourably assessed because they were not supported by any relevant studies in humans.[42]

[41] COMMISSION DECISION
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:161:0029:0033:EN:PDF

[42] NDA opinions on "General function" health claims under Article 13

8 Regulation

8.1.1 FSA Strategic Plan and Science and Evidence Strategy

At the end of March 2011 and following consultation (to which the Government Chemist made a detailed response[43]) the Food Standards Agency published its updated Strategy to 2015: Safer food for the nation. The strategy sets out six outcomes that the FSA will work towards to ensure that food is safe and that consumers can continue to have trust and confidence in the food they buy and eat. When the strategy was first published, in December 2009, there was a commitment to review it annually. This is the first update of the strategy, revised to reflect recent changes to the remit of the FSA, new information on allergens and, following the merger with the Meat Hygiene Service, a more extensive enforcement role for the FSA. The Agencies core principles were extended:

- putting the consumer first
- openness and transparency
- science and evidence-based
- acting independently
- *enforcing food law fairly*

the last (my emphasis) a new addition. After prompting by, among others, the Northern Ireland Food Advisory Committee the plan took account of the continuing responsibilities in Scotland and Northern Ireland with respect to nutrition and food standards.

To support the delivery of the updated strategy, the FSA also published its updated Science and Evidence Strategy 2010–2015.[44]

8.2 EFSA

8.2.1 EFSA Workplan 2011

EFSA plans to deliver approximately 900 scientific outputs and supporting publications in 2011. Two thirds of these now concern applications where EFSA evaluates regulated products in areas such as feed additives, enzymes, pesticides and health claims. EFSA aims to work more efficiently and involve Member States. For example, EFSA plans to outsource €8.3 million of activities to dedicated Member State organisations to assist it in data collection or other such preparatory work. The Authority will also keep Member States better informed of its medium-term plans to help them in forecasting their own risk assessment activities. It will continue to build relationships on a global basis. At an organisational level, in 2011 EFSA will be evaluated externally for the second time (the first was in 2005). It will measure the effectiveness of its Strategic Plan 2009-2013 and will also begin to use it's newly-developed corporate impact indicators to gauge the extent to which its work is having an impact on Europe's legislative processes. In addition, EFSA will begin to implement a thematic approach in its communications activities as outlined in its Communications Strategy 2010-2013. And as the year ends, EFSA will move to its new building in Parma.[45]

8.2.2 EFSA Information Exchange Platform (IEP)

The IEP was launched in 2008 to provide a platform for the Advisory Forum/Focal Point members and EFSA to facilitate the exchange of risk assessment outputs undertaken by official bodies in the different Member States. Access to the site is limited to certain groups of people. A step wise approach is taken to broadening access to the site following the decision

[43] FSA Strategic Plan Responses (accessed 25 July 2011)
http://www.food.gov.uk/multimedia/pdfs/consultationresponse/respfsarevstrategy20102015.pdf

[44] FSA, 2011, http://www.food.gov.uk/news/newsarchive/2011/mar/strategyto2015 accessed 25 July 2011

[45] EFSA, 2011, http://www.efsa.europa.eu/en/corporate/doc/wp11.pdf (accessed 25 July 2011)

of the Advisory Forum. Initially access was only granted to Focal Points and Advisory Forum members but has since been extended to nominated individuals, Candidate countries and EFSA Panels and units. In total 1165 people have access to the IEP site. These are Advisory Forum Members (including EFTA/EEC and observers; candidate countries, European Commission), Advisory Forum Communication Working Group Members, Focal Points Network Members (including observers; candidate countries), EFSA staff, All EFSA Panel Members, All EFSA Network Members and Nominated individual experts by the Advisory Forum. EFSA evaluated the IEP[46] with the main recommendations being:

- Access to the IEP site should be extended.
- Promotion activities should take place in collaboration with Member States.
- Improvements to the site are needed especially on the layout, structure and search function.
- The monthly reports should be widely and freely distributed to those involved in risk assessment activities.

Efforts should be made to access this information.

8.2.3 Electronic transmission of results of analytical measurement

The Hungarian Food Safety Information System (FSIS) provides an on-line link with the pesticide residue laboratories which submit the reports of the analyses directly to the central database. A report describes the operation of this system.[47]

8.2.4 Cyprus

Commission Implementing Regulation (EU) No 531/2011 of 31 May 2011 amended Regulation (EC) No 1480/2004 laying down specific rules concerning goods arriving from the areas not under the effective control of the Government of Cyprus in the areas in which the Government exercises effective control.[48]

9 Feeding Stuffs and Fertilisers

9.1 Undesirable Substances in Feed

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

Commission Regulation (EU) No 574/2011 of 16 June 2011 amended Annex I to Directive 2002/32/EC on maximum levels for nitrite, melamine, *Ambrosia* spp. and carry-over of certain coccidiostats and histomonostats and consolidating Annexes I and II thereto. [49]

The reasons for some of these interventions are interesting. In the case of nitrite it was found that the products and by- products from sugar beet and sugarcane and from starch production contain under certain conditions levels of nitrite exceeding the maximum levels recently established in Annex I to Directive 2002/32/EC. Furthermore, it appears that the method of analysis for the determination of nitrite in feed does not always provide reliable analytical results with regard to the products and by-products from sugar beet and sugarcane and from starch production. Given that the European Food Safety Authority (EFSA) concluded in its

[46] IEP Evaluation Report, EFSA, 2011, http://www.efsa.europa.eu/en/supporting/pub/134e.htm

[47] Electronic transmission of analytical data, http://www.efsa.europa.eu/en/supporting/doc/146e.pdf

[48] Commission: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:146:0004:0006:EN:PDF

[49] Commission Regulation (EU) No 574/2011 accessed 26 July 2011, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:159:0007:0024:EN:PDF

opinion of 25 March 2009[50] that the presence of nitrite in animal products does not raise any concern for human health, the products concerned are exempted for the time being from the maximum level for nitrite in feed materials, while nitrite levels in those products and appropriate methods of analysis are further examined.

As regards *Ambrosia* spp., EFSA concluded in its opinion of 4 June 2010 that bird feed may be an important means of *Ambrosia* spp. dispersal, especially in previously uninfested areas, as it often contains significant quantities of unprocessed seeds of *Ambrosia* spp. Therefore, the prevention of the use of bird feed contaminated with unprocessed seeds of *Ambrosia* spp. is likely to attenuate the further dispersal of *Ambrosia* spp. in the EU. *Ambrosia* spp. are of public health concern due to the allergenic properties of their pollen. Inhalation of the plant pollen may, amongst other conditions, cause rhino-conjunctivitis and asthma. There is also some evidence for allergenicity of *Ambrosia* spp. pollen in animals. It is therefore appropriate to limit the presence of *Ambrosia* spp. seeds in feed materials and compound feed containing unground grains and seeds and to establish a maximum level of *Ambrosia* spp. seeds in unground grains and seeds as low as reasonably achievable (ALARA) by good agricultural practices and cleaning techniques.

9.1.2 Catalogue of feed materials

Commission Regulation (EU) No 575/2011 of 16 June 2011 was made on the Catalogue of feed materials. [51]

9.2 Feed Additives

Commission Implementing Regulation (EU) No 371/2011 of 15 April 2011 was made concerning the authorisation of dimethylglycine sodium salt as feed additive for chickens for fattening (holder of the authorisation Taminco N.V.).[52]

Commission Implementing Regulation (EU) No 388/2011 of 19 April 2011 was made concerning the authorisation of maduramicin ammonium alpha as a feed additive for chickens for fattening (holder of authorisation Alpharma (Belgium) BVBA) and amending Regulation (EC) No 2430/1999.[53]

Commission Implementing Regulation (EU) No 389/2011 of 19 April 2011 was made concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase, subtilisin and alpha-amylase as feed additive for laying hens (holder of authorisation Danisco Animal Nutrition).[54]

Commission Implementing Regulation (EU) No 406/2011 of 27 April 2011 was made amending Regulation (EC) No 2380/2001 as regards the composition of the feed additive maduramicin ammonium alpha.[55]

Commission Implementing Regulation (EU) No 515/2011 of 25 May 2011 was made concerning the authorisation of vitamin B6 as a feed additive for all animal species.

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[50] EFSA Panel on Contaminants in the Food Chain, Scientific Opinion on Nitrite as undesirable substances in animal feed, The EFSA Journal (2009) 1017, 1-47. Available online:
http://www.efsa.europa. eu/en/scdocs/doc/1017.pdf

[51] Catalogue of feed materials
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:159:0025:0065:EN:PDF

[52] Commission Implementing Regulation (EU) No 371/2011
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:102:0006:0007:EN:PDF

53 Commission Implementing Regulation (EU) No 388/2011
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:104:0003:0006:EN:PDF

[54] Commission Implementing Regulation (EU) No 389/2011
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:104:0007:0009:EN:PDF

[55] Commission Implementing Regulation (EU) No 406/2011
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:108:0011:0012:EN:PDF

Commission Implementing Regulation (EU) No 516/2011 of 25 May 2011 amended Regulation (EC) No 600/2005 as regards the use of the preparation of Bacillus licheniformis DSM 5749 and Bacillus subtilis DSM 5750 in feed containing formic acid.[56]

Commission Implementing Regulation (EU) No 527/2011 of 30 May 2011 was made concerning the authorisation of a preparation of endo-1,4-β-xylanase produced by Trichoderma reesei (MUCL 49755), endo-1,3(4)-β-glucanase produced by Trichoderma reesei (MUCL 49754) and polygalacturonase produced by Aspergillus aculeatus (CBS 589.94) as feed additive for weaned piglets (holder of the authorisation Aveve NV).[57]

Commission Implementing Regulation (EU) No 389/2011 of 19 April 2011 was made concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase, subtilisin and alpha-amylase as feed additive for laying hens (holder of authorisation Danisco Animal Nutrition). [58]

[56] Commission Implementing Regulation (EU) No 516/2011
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:138:0043:0044:EN:PDF

57 Commission Implementing Regulation (EU) No 527/2011
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:143:0006:0009:EN:PDF

[58] Commission Implementing Regulation (EU) No 389/2011
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:143:0006:0009:EN:PDF