

# European and UK Regulation of Food and Feed

Review

October 2011 – March 2012

Statutory Analysis

Government Chemist Programme

LGC/R/2012/240

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Report:

**European and UK  
Regulation of  
Food and Feed**

Review  
October 2011 – March 2012

Statutory Analysis  
Government Chemist  
Programme

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## Introduction

This report, covering the period October 2011 to March 2012, is the third<sup>1</sup> of a 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 includes general contextual issues in food and feed. The 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 first 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<sup>2</sup> complements the reports in this 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 October 2011 will not necessarily be reiterated herein; please refer to previous 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.

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<sup>1</sup> For the second review covering July – Sept 2011 see <http://www.governmentchemist.org.uk/Generic.aspx?m=77&amid=1432> and <http://www.governmentchemist.org.uk/Generic.aspx?m=77> for previous editions

<sup>2</sup> Boley N. 2012 Government Chemist Legislation - Annual statement of statutory scope, available at <http://www.governmentchemist.org.uk/Generic.aspx?m=77&amid=1401> (accessed 13.07.12)

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, recitals that form the introduction to European measures and abstracts published by EFSA. Full acknowledgements and references are given as footnotes with links to the original document.

## Acknowledgements

Funding under the BIS National Measurement Office <sup>3</sup> funded Government Chemist Programme 2011-2014 is gratefully acknowledged.

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<sup>3</sup> The National Measurement Office, <http://www.nmo.bis.gov.uk/>

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## Cross-Cutting Issues

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### ***Emerging Risks***

EFSA established the Emerging Risks Unit to identify and assess the relevance of potential new threats to food and feed safety and asked the Unit to establish a working group for the evaluation and further development of a transparent and sustainable emerging risk identification framework. The main tasks of the working group include the identification of selected methods that could be applied by EFSA, indications on possible implications for strategic planning and policy making, and approaches for validating the proposed framework. The group, in February 2012, published a report “Towards a methodological framework for emerging risk identification”. The working group identified the need for an improvement of the current approach, in particular through optimisation of the terminology used, *i.e.* differentiation between “emerging issues” and “emerging risks”. The report sets out recommendations for more efficient selection and prioritisation of data sources to improve the efficiency and transparency of the collection of information, the formalisation of the outputs and follow-up actions. Further, a standing working group is proposed including experts from the Scientific Committee and Panels as well as selected EFSA’s staff, to work closely with the Emerging Risks Unit and the EFSA Network on Emerging Risks (*i.e.* EREN) and other Community Agencies should be further encouraged to become active partners.<sup>4</sup>

### **Trends in trade**

Evaluation of trends in trade patterns can be used to aid prediction of emerging risks and EFSA demonstrated automatic scanning of Eurostat’s Comext database to achieve this.<sup>5</sup>

### ***Food Labelling and machinery of Government changes***

The new food labelling regulation (1169/2011) referred to elsewhere, a major change to the way in which food is labelled, will involve activity by Defra, FSA, Department of Health and Local Authorities.

Further to details of changes to the machinery of Government noted in previous editions of this review the Transfer of Functions (Food) Regulations 2011,<sup>6</sup> which apply to England, amend the Medical Food (England) Regulations 2000, the Notification of Marketing of Food for Particular Nutritional Uses (England) Regulations 2007, the Nutrition and health Claims (England) Regulations 2007 and the Infant Formula and Follow-on Formula (England) Regulations 2007, by transferring functions under each set of Regulations from the Food Standards Agency to the Secretary of State for Health.

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<sup>4</sup> European Food Safety Authority; Towards a methodological framework for emerging risk identification. Supporting Publications 2012:EN-243. [42 pp.]. Available at <http://www.efsa.europa.eu/en/supporting/pub/243e.htm> (accessed 10.07.12)

<sup>5</sup> European Food Safety Authority; Evaluation of a system for the scanning of Eurostat’s data to detect trends in trade. Supporting Publications 2011: EN-219. [90 pp.] Available at <http://www.efsa.europa.eu/en/supporting/pub/219e.htm> (accessed 10.07.12)

<sup>6</sup> The Transfer of Functions (Food) Regulations 2011, <http://www.legislation.gov.uk/uksi/2011/3012/made/data.pdf> accessed 23.01.12.

The above developments suggest we will need to be aware of the initiatives of Defra and Department of Health as well as FSA in the future.

## ***European Food Consumption Database Pilot***

Food consumption information plays an important role in risk assessment. EFSA has completed two projects to collect and publish concise followed by comprehensive food consumption data, varying in the degree of detail of the food levels reported. A report of a pilot concluded that an EU Usual Intakes database, which is representative of the correlated food intake of the combined member states, is feasible and makes recommendations for its realisation.<sup>7</sup>

## ***Radionuclide levels in food products from Japan***

### **Special conditions relaxed**

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 replaced by Commission Implementing Regulation (EU) No 961/2011 of 27 September 2011.<sup>8</sup> Following improved conditions in Japan a reduction of the frequency of import controls was allowed by Commission Implementing Regulation (EU) No 1371/2011 of 21 December 2011.<sup>9</sup> This Regulation also recognised that with a short half-life (about 8 days), no new releases and no further positives the requirement for the analysis for the presence of iodine- 131 was no longer required. Continued improvements permitted further reductions in control measures on imported food in March 2012 and 961/2011 was extended until 31 October 2012.<sup>10</sup> However at the end of March Regulation No 961/2011 having been amended several times was replaced by Commission Implementing Regulation (EU) No 284/2012 of 29 March 2012 to similar effect.<sup>11</sup> The changes include exclusion of sake, whiskey and shochu from the scope of the Regulation (no positive findings) and harmonisation with new Japanese maximum levels for the sum of caesium-134 and caesium-137 which are lower than the maximum levels established by Council Regulation (Euratom)

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<sup>7</sup> Paul Dempsey, Creme Software Ltd, Scientific Report submitted to EFSA, 2012, Pilot project to test the feasibility of the development of a “Compiled European Food Consumption Database, available at <http://www.efsa.europa.eu/en/supporting/pub/238e.htm> (accessed 10.07.12)

<sup>8</sup> 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>

<sup>9</sup> Commission Implementing Regulation (EU) No 1371/2011 of 21 December 2011 amending Implementing Regulation (EU) No 961/2011 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:2011:341:0041:0044:EN:PDF> accessed 23.01.12.

<sup>10</sup> Commission Implementing Regulation (EU) No 250/2012 of 21 March 2012 amending Implementing Regulation (EU) No 961/2011 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:2012:082:0003:0004:EN:PDF> (accessed 20.06.12)

<sup>11</sup> Commission Implementing Regulation (EU) No 284/2012 of 29 March 2012 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 Implementing Regulation (EU) No 961/2011 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:092:0016:0023:EN:PDF> (accessed 21.06.12)



No 3954/87. Finally controls on strontium, plutonium and americium radionuclides have been removed given that the affected nuclear reactor is now in a stable situation and the possibility of new releases of such radioactivity sources is minimal.

### ***Radionuclide levels in sheep following the Chernobyl incident***

An order was made in 2011 that partially revokes the Food Protection (Emergency Prohibitions) (Radioactivity in Sheep) (Wales) Order 1991. That Order contains emergency prohibitions restricting various activities in order to prevent human consumption of food which has been, or which may have been, rendered unsuitable for that purpose in consequence of the escape of radioactive substances from a nuclear reactor situated at Chernobyl in the Ukraine. This partial revocation reduces the area subject to restrictions.<sup>12</sup>

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<sup>12</sup> The Food Protection (Emergency Prohibitions) (Radioactivity in Sheep) (Wales) (Partial Revocation) Order 2011 <http://www.legislation.gov.uk/wsi/2011/2759/made/data.pdf>

## Food Safety

### **Regulated Contaminants in Food**

A [consolidated version](#) of Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs was produced in 2012.

### **Mycotoxins**

#### **Aflatoxins in cereals in the EU and climate change**

EFSA's Emerging Risks Unit identified changing patterns in mycotoxin contamination in cereals such as wheat, maize and rice, due to climate change as a potential emerging hazard. Hence a study was commissioned from a large consortium of research groups on the prediction of the emergence of aflatoxins (AF) in cereals in the EU due to climate change. The risk of AF contamination was predicted in various climate change scenarios. Predictions showed a reduction in season length and an advance in flowering and harvest dates for all the crops considered; this could allow an enlargement of the crop growing areas towards the north of EU, mainly for maize and rice, because earlier ripening would then be possible in these areas.

Risk maps were produced and can be used as a communication tool to reinforce prevention of AF risks by identifying priority locations for intervention. The predictions confirmed that maize is the cereal crop of concern and that both human and animal populations could be exposed to a high AF risk, at least in some EU regions. Wheat would present a negligible AF risk and rice no risk at all. However, the estimated AF risk could not be quantitatively correlated to EU legal maximum levels for AF contamination.<sup>13</sup>

#### **T-2 and HT-2 toxins**

T-2 toxin and HT-2 toxin are mycotoxins produced by various *Fusarium* species. The European Commission asked EFSA for a scientific opinion on the risk to human and animal health related to the presence of T-2 and HT-2 toxin in food and feed. A total of 20,519 results for the sum of T-2 and HT-2 toxins in food, feed and unprocessed grains, collected in 2005-2010 from 22 European countries, were used in the evaluation. The highest mean concentrations for the sum of T-2 and HT-2 toxins were observed in grains and grain milling products, notably in oats and oat products. Grains and grain-based foods, in particular bread, fine bakery wares, grain milling products, and breakfast cereals, made the largest contribution to the sum of T-2 and HT-2 toxin exposure for humans. T-2 toxin is rapidly metabolised to a large number of products, HT-2 toxin being a major metabolite. Pigs are amongst the most sensitive animals towards the effects of T-2 toxin, the most sensitive endpoints being immunological or haematological effects.<sup>14</sup>

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<sup>13</sup> Modelling, predicting and mapping the emergence of aflatoxins in cereals in the EU due to climate change, 2012, available at <http://www.efsa.europa.eu/en/supporting/pub/223e.htm> (accessed 10.07.12)

<sup>14</sup> EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on risks for animal and public health related to the presence of T-2 and HT-2 toxin in food and feed. EFSA Journal 2011;9(12):2481. [187 pp.] doi:10.2903/j.efsa.2011.2481. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2481.htm> (accessed 10.07.12)

## ***Other regulated contaminants***

### **Cadmium**

EFSA in January 2012 produced a report on cadmium dietary exposure in Europe. Cadmium can cause kidney failure and has been statistically associated with an increased risk of cancer. Food is the dominating source of human exposure in the non-smoking population. The Joint FAO/WHO Expert Committee on Food Additives established a provisional tolerable monthly intake of 25 µg/kg body weight, whereas the EFSA Panel on Contaminants in the Food Chain nominated a tolerable weekly intake of 2.5 µg/kg body weight to ensure sufficient protection of all consumers. Better to identify major dietary sources, cadmium levels in food on the European market were reviewed and exposure estimated using detailed individual food consumption data. High levels of cadmium were found in algal formulations, cocoa-based products, crustaceans, edible offal, fungi, oilseeds, seaweeds and water molluscs. The report confirmed that children and adults at the 95<sup>th</sup> percentile exposure could exceed health-based guidance values.<sup>15</sup>

### **Dioxins, furans and PCBs**

#### **Dioxin limits revised**

Dioxins and related compounds are regulated by a number of measures. Commission Regulation (EC) No 1881/2006 of 19 December 2006 sets maximum limits in certain foodstuffs. Commission Recommendation 2011/516/EU of 23 August 2011, aimed to reduce levels of these compounds, sets out action levels in order to stimulate a pro-active approach to reduce the presence of polychlorinated dibenzo-para-dioxins and polychlorinated dibenzofurans (PCDD/Fs) and dioxin-like PCBs in food. Action levels are a tool to highlight where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination.

Dioxins belong to a group of 75 polychlorinated dibenzo-p-dioxin (PCDD) congeners and 135 polychlorinated dibenzofuran (PCDF) congeners, of which 17 are of toxicological concern. Polychlorinated biphenyls (PCBs) are a group of 209 different congeners which can be divided into two groups according to their toxicological properties: 12 congeners exhibit toxicological properties similar to dioxins and are therefore often referred to as 'dioxin-like PCBs' (DL-PCB). The other PCBs do not exhibit dioxin-like toxicity but have a different toxicological profile and are referred to as 'non dioxin-like PCB' (NDL-PCB). Each congener of dioxins or DL-PCBs exhibits a different level of toxicity. In order to be able to sum up the toxicity of these different congeners, the concept of toxic equivalency factors (TEFs) was introduced to facilitate risk assessment and regulatory control. As a result the analytical results relating to all the individual dioxin and dioxin-like PCB congeners of toxicological concern are expressed in terms of a quantifiable unit, namely the TCDD toxic equivalent (TEQ). The World Health Organisation (WHO) held an expert workshop on 28 to 30 June 2005 concerning the TEF values, agreed by WHO in 1998. A number of TEF values were changed, Data on the effect of the new TEF values and the recent occurrence of dioxins were reviewed by EFSA with the result that revised maximum levels of PCBs have been proposed. Temporary derogations for certain fish from the Baltic marketed in Finland, Sweden and

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<sup>15</sup> European Food Safety Authority; Cadmium dietary exposure in the European population. EFSA Journal 2012;10(1):2551. [37 pp.] doi:10.2903/j.efsa.2012.2551. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2551.htm> (accessed 10.07.12)

Latvia have been made 'permanent' and limits have been established for the first time for foods with less than 2 % fat.<sup>16</sup> The situation will be kept under review.

### **Dioxin sampling and analysis**

Methods of sampling and analysis for official control laid down by Commission Regulation (EC) No 1883/2006 of 19 December 2006 have been reviewed and harmonised in light of the application of new maximum levels for non-dioxin-like PCBs and the need to update criteria for screening methods. Accordingly Regulation 1883/2006 has been replaced as of 13 April 2012 by Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs.<sup>17</sup> The Regulation establishes appropriate requirements for a bioanalytical screening method ensuring a false-compliant rate below 5 % and strict requirements for confirmatory methods of analysis. The requirement for a referee analysis is recognised in the Regulation which requires replicate samples for enforcement, defence and reference purposes from the homogenised aggregate sample. Clear criteria for acceptance and rejection of consignments are set out. Typically a lot is accepted if the analytical result does not exceed the maximum concentration laid down in Regulation 1881/2006 taking into account the measurement uncertainty. The lot is non-compliant with Regulation (EC) No 1881/2006, if the upperbound analytical result confirmed by duplicate analysis exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty. Measurement uncertainty (U) may be taken into account either (A) by "using a coverage factor of 2 which gives a level of confidence of approximately 95 %" or (B) by establishing the decision limit (CC $\alpha$ ) according to Decision 2002/657/EC (point 3.1.2.5 of Annex I to that Decision — the case of substances with an established permitted level). A lot is non-compliant if the measured value is equal to or above the CC $\alpha$ . These rules apply for the analytical result obtained on the sample for official control. In case of analysis for defence or reference purposes, the Regulation allows national rules apply; however, to the best of our knowledge there are no specific national rules in the UK. As is now common practice in referee cases the Regulation requirements would be followed and it is likely that we would apply approach 'A' to the estimation of U. Rules are also given for interpretation of exceedance of action levels. Recognising that in fish of the same species originating from the same region, the level of dioxins, dioxin-like PCBs and non-dioxin-like PCBs can be different depending on the size and/or the age of the fish and that the level of dioxins, dioxin-like PCBs and non-dioxin-like PCBs is not necessarily the same in all parts of the fish, sampling and sample preparation is specified in order to ensure a harmonised approach throughout the EU. The new provisions relate to the sampling and analysis of dioxins, dioxin-like PCBs and non-dioxin-like PCBs for the implementation of Regulation (EC) No 1881/2006. They do not affect the sampling strategy, sampling levels and frequency as specified in Annexes III and IV to Council Directive 96/23/EC of 29 April 1996 nor the targeting criteria for sampling as laid down in Commission Decision 98/179/EC of 23 February 1998.

### **Dioxin monitoring extended**

Commission Regulation (EU) No 225/2012 of 15 March 2012 amended Annex II to Regulation (EC) No 183/2005 of the European Parliament and of the Council as regards the approval of establishments placing on the market, for feed use, products derived from vegetable oils and blended fats and as regards the specific requirements for production, storage, transport and dioxin testing of oils, fats and products derived thereof.<sup>18</sup> Successive feed incidents involving dioxins have contributed to interlinked regulations aimed to ensure control,

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<sup>16</sup> Commission Regulation (EU) No 1259/2011 of 2 December 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs in foodstuffs <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:320:0018:0023:EN:PDF> accessed 23.01.12.

<sup>17</sup> Commission Regulation (EU) No 252/2012 of 21 March 2012 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:084:0001:0022:EN:PDF> (accessed 21.06.12)

<sup>18</sup> Commission Regulation (EU) No 225/2012 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:077:0001:0005:EN:PDF> (accessed 20.06.12)

traceability and consumer protection. Regulation 767/2009 requires feed placed on the market to be safe and explicitly labelled with the respective type of feed and Regulation 575/2011 on the Catalogue of feed materials lists detailed descriptions for specific feed materials to be used for labelling purposes. Regulation (EC) No 1831/2003 lays down general rules on feed hygiene, processing and the registration of feed business establishments. Feed business operators lower down the feed chain have the obligation to source feed only from establishments which are registered or approved. The Commission have extended by Regulation No 225/2012 the requirement for approval to establishments processing crude vegetable oils, manufacturing products derived from oils of vegetable origin, blending fats and producing biodiesel if these products are intended for use in feed. The amendment further requires HACCP for the production, labelling, storage and transport of such feed materials

It includes an obligation for feed business operators to test fats, oils and products derived thereof for dioxin and dioxin-like PCBs and detailed provisions on sampling and analysis not contained in this Regulation should remain within the competence of the Member States. Furthermore, Member States are encouraged to focus on the controls of feed business operators that are not under the scope of the dioxin monitoring but that obtain the products mentioned above.

Laboratories performing dioxin analyses are obliged to report results exceeding the maximum permitted limits provided for in Directive 2002/32/EC not only to the feed business operator but also to the competent authority. This does not exempt the feed business operator from his obligation to inform the competent authority.

## Ergot

Ergot is a fungal structure (*Claviceps* species) that parasitises grain or grasses as large dark coloured sclerotia containing alkaloids, the most prominent being ergometrine, ergotamine, ergosine, ergocristine, ergocryptine and ergocornine and their related -inines. The amount and toxin pattern vary between fungal strains, depending on the host plant and the geographical region. The ergot alkaloids are among the most important natural pharmaceuticals and toxins in human history having been used for medical benefit and illicitly for psychedelic recreation. Unknowing ingestion has led to mass poisoning with dire physiological and social implications.<sup>19</sup> Directive 2002/32/EC on undesirable substances in animal feed limits rye ergot (*Claviceps purpurea*) sclerotia to a maximum of 1 000 mg/kg in feed containing unground cereals. At present more data are needed to identify all factors responsible for the variability in ergot alkaloid pattern in individual plant species. The physical determination of the contamination rate of cereals by rye ergot is often inaccurate, and is impossible in processed feed and food. Hence control by chemical analysis is suggested although the methods are confined to a selected number of ergot alkaloids.

The Commission has recommended<sup>20</sup> that Member States should, with the active involvement of feed and food business operators, monitor the presence of ergot alkaloids in cereals and cereal products intended for human consumption or intended for animal feeding, in pasture/forage grasses for animal feeding and in compound feed and food. Analysis should be for at least the following ergot alkaloids:

- ergocristine/ergocristinine,
- ergotamine/ergotaminine,
- ergocryptine/ergocryptinine,

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<sup>19</sup> Christopher L. Schardl, Daniel G. Panaccione, And Paul Tudzynski, 2006, Ergot Alkaloids – Biology and Molecular Biology, The Alkaloids, Vol. 63, ISSN: 1099-4831, DOI: 10.1016/S1099-4831(06)63002-2, Elsevier Inc. [http://bitnest.ca/Silo42/10.1016/S1099-4831\(06\)63002-2.pdf](http://bitnest.ca/Silo42/10.1016/S1099-4831(06)63002-2.pdf) (accessed 20.06.12)

<sup>20</sup> Commission Recommendation of 15 March 2012 on the monitoring of the presence of ergot alkaloids in feed and food <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:077:0020:0021:EN:PDF>

- ergometrine/ergometrinine,
- ergosine/ergosinine,
- ergocornine/ergocorninine.

Simultaneous determination, if possible, of the sclerotia content would improve knowledge of the relation between the content of sclerotia and the level of individual ergot alkaloids. The analytical results should be provided on a regular basis to EFSA for compilation into a database.

## Nitrates

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs sets maximum levels for nitrates in certain leafy vegetables. In some cases, despite developments in good agricultural practice, the maximum levels are exceeded and therefore a temporary derogation was granted to certain Member States for nitrate levels higher than the established maximum levels. Further research has not resolved this problem. EFSA has estimated that since overall, including for infants and children, the estimated exposures to nitrate from vegetables are thought unlikely to result in appreciable health risks, the recognised beneficial effects of consumption of vegetables should prevail. It was therefore thought appropriate slightly to increase the maximum level for nitrates in fresh spinach and lettuce without endangering public health. The new maxima apply from 23<sup>rd</sup> December 2011. A new maximum is set for Rucola (rocket) applying from 1st April 2012.<sup>21</sup>

## Polycyclic aromatic hydrocarbons

No further developments in the period

## Other Contaminants

### Citrinin

EFSA in March 2012 issued a scientific opinion on the health risks from citrinin in food and feed. Citrinin is a mycotoxin produced by several species of the genera *Aspergillus*, *Penicillium* and *Monascus* and occurs mainly in stored grains. The opinion gives detailed information (from a limited dataset) on citrinin occurrence in food and its toxicology but the CONTAM Panel concluded that the impact of uncertainties on the risk assessment is large, and more data regarding the toxicity and the occurrence of citrinin in food and feed in Europe are needed to enable refinement of the risk assessment. Citrinin is known to occur also as an undesirable contaminant in *Monascus* fermentation products (generally described as red mould rice (RMR)), which have been used in Asia for centuries for meat preservation and food colouring. Instrumental techniques for citrinin analysis include fluorimetric, chromatographic and immunochemical techniques. To date, high performance liquid chromatography with fluorescence detection is the method of choice for routine citrinin analysis. Limits of detection (LOD) as low as 0.1 µg/kg can be achieved. One of the major challenges in citrinin analysis relates to its instability in various organic solvents and at higher temperatures. So far, none of the applied analytical methods has been validated by inter-laboratory studies. In addition, no certified reference materials or proficiency tests are available for the determination of citrinin in food or feed.<sup>22</sup>

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<sup>21</sup> Commission Regulation (EU) No 1258/2011 of 2 December 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for nitrates in foodstuffs, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:320:0015:0017:EN:PDF> accessed 23.01.12.

<sup>22</sup> EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on the risks for public and animal health related to the presence of citrinin in food and feed. EFSA Journal

## Phomopsins

In February EFSA published a Scientific Opinion on the risks for animal and public health related to the presence of phomopsins in feed and food. The opinion describes phomopsins as a family of mycotoxins produced by the fungus *Diaporthe toxica* (formerly referred to as *Phomopsis leptostromiformis*). Lupins are the main host for the fungus, and infected stubble is the major source of animal exposure. Lupin seed is used in food and feed production, but the extent is poorly documented and data on the occurrence of phomopsins in lupin-based foods and feeds are limited. Therefore, it was not possible to assess dietary intake of phomopsins. Phomopsins are modified polypeptides, which bind with high affinity to tubulin isotypes and disrupt microtubular functions. Phomopsin A, the major toxic congener, is hepatotoxic in all animal species tested at sufficient doses. Phomopsin A is also hepatocarcinogenic in rats. The absence of either dose-response information on toxicities associated with phomopsins or exposure/occurrence data precludes an assessment of human or animal risks. However, the severity of toxicities in numerous animal species suggests that human and livestock exposures should be kept as low as possible. Currently five phomopsins have been identified, namely A, B, C, D and E, with phomopsin A being considered the main toxic metabolite. The EFSA Panel on Contaminants in the Food Chain concluded that, before meaningful progress can be made, validated analytical methods for the identification and quantification of the major toxic phomopsin congeners in foodstuffs, livestock feeds, and fluids/tissues from dosed animals must be developed. The EFSA report cites quantitative methods of analysis for phomopsins in food to include:

- Enzyme-Linked-Immuno-Sorbent Assay (ELISA)
- High performance liquid chromatography (LC)
- Nursling rat bioassay (NRB)

FAB mass spectrometry has been used to confirm the identity of phomopsins and to determine the amino acid constituents and sequence. FAB mass spectrometry could, either in combination with LC or alone, provide a useful method of detection and analysis of phomopsins in food extracts. It has also been suggested that measurement of 3,4-dehydroproline in acid hydrolysates of sample extracts may provide a specific method of quantitating phomopsins in foods since this amino acid has not been isolated from any other natural sources and is a stable product measurable by several physicochemical methods.<sup>23</sup>

## Tetrabromobisphenol A (TBBPA) flame retardant

EFSA was tasked by the Commission to deliver a scientific opinion on tetrabromobisphenol A (TBBPA) and its derivatives in food and issued a report in January 2012. TBBPA and its derivatives are widely used as flame retardants. Data from the analysis of TBBPA in 344 food samples were submitted to EFSA by two European countries (Norway and Spain), covering the period from 2007 to 2010. All samples were in the food group “Fish and other seafood”, and all analytical results were reported as less than the limit of quantification (LOQ) (about 1 ng/g wet weight). Toxicological studies with TBBPA have been carried out and its main target is thyroid hormone homeostasis. TBBPA is not genotoxic nor are there indications that it might be carcinogenic. The CONTAM Panel concluded that current dietary exposure to TBBPA in the European Union does not raise a health concern. Also exposure of infants via human milk does not raise a health concern. Additional exposure, particularly of young children, to TBBPA from house dust is unlikely to raise a health concern.<sup>24</sup>

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2012;10(3):2605. [82 pp.] doi:10.2903/j.efsa.2012.2605. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2605.htm> (Accessed 04.07.12)

<sup>23</sup> EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on the risks for animal and public health related to the presence of phomopsins in feed and food. EFSA Journal 2012;10(2):2567. [52 pp.] doi:10.2903/j.efsa.2012.2567. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2567.htm> (accessed 10.07.12)

<sup>24</sup> EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Tetrabromobisphenol A (TBBPA) and its derivatives in food. EFSA Journal 2011;9(12):2477. [61 pp.] doi:10.2903/j.efsa.2011.2477. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2477.htm> (accessed 10.07.12)

## **Bulk edible oils & fats - acceptable previous cargoes**

Shipping of edible fats and oils into Europe is permitted in bulk tanks, in which substances, included in a positive list, had been previously transported. The European Commission requested EFSA to evaluate the list of substances in the Annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils. The first of three scientific opinions was published by the Panel on Contaminants in the Food Chain (CONTAM Panel) in January 2012, in which thirteen of these substances have been evaluated. The CONTAM Panel concluded that phosphoric acid, ammonium polyphosphate, benzyl alcohol (pharmaceutical and reagent grades only), epoxidised soyabean oil (with a minimum 7 % - maximum 8 % oxirane oxygen content), ethyl acetate, 2-ethylhexanol, 1,3-butanediol, 1,4-butanediol, propylene glycol, polypropylene glycol (molecular weight greater than 400), methanol and ethanol, would not be of health concern as previous cargoes. In the case of calcium lignosulphonate, there was sufficient information available for the CONTAM Panel to conclude that the risk from short-term exposure to this substance itself, when used as a previous cargo, would not give rise to any toxicological concern. However, the product varies markedly in composition, there is no information on potential impurities, nor is there information on its potential reactivity with fats and oils. The CONTAM Panel therefore concluded that calcium lignosulphonate does not meet the criteria for acceptability as a previous cargo.<sup>25</sup>

## **Food Allergens**

The major changes in the period were the changes in labelling (from December 2014) invoked by the new Food Information Regulation (see below).

## **Food Additives**

### **New Regulation on Food Additives**

Regulation (EC) No 1333/2008 provides for the establishment of a list of food additives approved for use in the EU in foods and their conditions of use. Food additives which are currently permitted for use in foods under Directive 94/35/EC of 30 June 1994 on sweeteners, Directive 94/36/EC of 30 June 1994 on colours and Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners must be included in Annex II to Regulation (EC) No 1333/2008 after a review of their compliance with Articles 6, 7 and 8 thereof and a new risk assessment by EFSA. Food additives and uses which are no longer needed will not be included in Annex II. In November 2011 Commission Regulation (EU) No 1129/2011 was made amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives.<sup>26</sup> The new Annex II applies from 1 June 2013, and the Annexes to Directive 94/35/EC, Directive 94/36/EC and Directive 95/2/EC will cease to apply from 1 June 2013. Regulation (EC) No 884/2007 is repealed as from 1 June 2013. Foods that have been lawfully placed on the market before 1 June 2013, but do not comply with this regulation, may continue to be marketed until their date of minimal durability or use-by-date.

The Regulation includes a new food categorisation system based on the established *Codex Alimentarius* General Standard for Food Additives food category system to list food additives

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<sup>25</sup> EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on the evaluation of the substances currently on the list in the Annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils – Part I of III. EFSA Journal 2011;9(12):2482. [61 pp.] doi:10.2903/j.efsa.2011.2482. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2482.htm> (accessed 10.07.12)

<sup>26</sup> Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 (food additives), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0001:0177:EN:PDF> accessed 22.01.12.



in groups for authorisation. Certain food colours, often no longer in use, have not been maintained in the new permitted list and other changes made including clarification of the exception to the carry-over principle in a compound food. Changes are made with regard to basic methacrylate copolymer (E 1205) and silicon dioxide (E 551) in salt substitutes.

In the recitals to the regulations the Commission signalled its intention to limit exposure to aluminium containing additives. The recital also clarifies that limits on nitrites apply at the end of the production process. In addition, the Commission will consult Member States, stakeholders and EFSA to discuss the possibility of reducing the current maximum nitrite limits in all meat products and to further simplify the rules for traditionally manufactured products. Depending on the outcome of such consultation, the Commission will consider whether it is appropriate to propose an adaptation to the maximum levels of nitrites that may be added to certain meat products.

## Steviol glycosides

Annex II was further amended by Commission Regulation (EU) No 1131/2011 of 11 November 2011<sup>27</sup> that provides for maximum limits for steviol glycosides in food.

## Additives in food additives, enzymes and flavourings

Commission Regulation (EU) No 1130/2011 of 11 November 2011<sup>28</sup> amended Annex III to Regulation (EC) No 1333/2008 by establishing a list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients and their conditions of use. The list includes carriers and “nutrients” for the purposes of this Annex means vitamins, minerals and other substances added for nutritional purposes, as well as substances added for physiological purposes as covered by Regulation (EC) No 1925/2006, Directive 2002/46/EC, Directive 2009/39/EC and Regulation (EC) No 953/2009.

## Colours

Commission Regulation (EU) No 232/2012 of 16 March 2012 further amending Annex II to Regulation (EC) No 1333/2008 as regards the conditions of use and the use levels for Quinoline Yellow (E 104), Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124).<sup>29</sup>

In order to ensure that revised (temporary) ADIs for the following colours are not exceeded the conditions of use and maxima have been revised. Permitted maxima in most cases have been reduced although there are exceptions for some traditional products which do not significantly contribute to the exposure. Some provisions have also been deleted. E 104, Quinoline Yellow, E 110, Sunset Yellow FCF/Orange yellow S and E 124 Ponceau 4R, Cochineal red A are removed from Annex II Part C point (3) – the list of food colours with a combined maximum limit however the combined maximum limit when the colours are used together with the remaining colours in Group III should be maintained. The Regulation will apply from 1 June 2013 and foods that have been lawfully placed on the market before 1 June 2013 but that do not comply may continue to be marketed until stocks are exhausted.

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<sup>27</sup> Annex II was further amended by Commission Regulation (EU) No 1131/2011 of 11 November 2011 with regard to steviol glycosides <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0205:0211:EN:PDF> accessed 23.01.12.

<sup>28</sup> Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients, available at: <http://eur-lex.europa.eu/Notice.do?val=625734:cs&lang=en&list=627518:cs,627549:cs,627517:cs,625734:cs.&pos=4&page=1&nbl=4&pgs=10&hwords=> accessed 23.01.12

<sup>29</sup> Commission Regulation (EU) No 232/2012 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:078:0001:0012:EN:PDF> (accessed 20.06.12)

## Consolidated version

A consolidated version of Regulation 1333/2008 on food additives is [available](#)

## Specifications for food additives

Criteria for origin, purity and other aspects of a range of food additives, including colours, preservatives, antioxidants and general additives were revised by Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.<sup>30</sup> The revisions take into account JECFA and EFSA recommendations. Specifications cited in Commission Directive 2008/128/EC of 22 December 2008 (colours), Commission Directive 2008/84/EC of 27 August 2008 (food additives other than colours and sweeteners) and Commission Directive 2008/60/EC of 17 June 2008 (sweeteners) have been updated and taken over to this Regulation and those Directives are repealed.

## Aluminium in Food

See above Regulation 1129/2011

## Caramel and imidazoles

In February 2012 the US Centre for Science in the Public Interest petitioned the FDA to bar the use of caramel produced with ammonia and containing the alleged carcinogens 2-methylimidazole and 4-methylimidazole.

## BHT safety re-evaluation

The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) in March 2012 gave an opinion re-evaluating the safety of butylated hydroxytoluene (BHT, E 321), an authorised synthetic antioxidant that was previously evaluated by JECFA (1996) and the EU Scientific Committee for Food (SCF) in 1987. The SCF established an ADI of 0-0.05 mg/kg bw/day based on thyroid, reproduction and haematological effects in the rat. JECFA allocated an ADI of 0-0.3 mg/kg bw/day for BHT based on effects in the reproduction segments and hepatic enzyme induction seen in two separate 2-generation studies in rats. The Panel concluded that BHT is not of concern with respect to genotoxicity and that any carcinogenicity would be thresholded. Overall, the Panel concluded that more recent studies suggest revision of the ADI of 0.05 mg/kg bw/day. Based on a No Observed Adverse Effect Level, NOAEL, of 25 mg/kg bw/day and an uncertainty factor of 100, the Panel derived an ADI of 0.25 mg/kg bw/day. Since the NOAEL of 25 mg/kg bw/day is below the BMDL10<sup>31</sup> value of 247 mg/kg bw/day derived from the data for the incidence of hepatocellular carcinomas in male rats, the Panel concluded that this NOAEL also covers the hepatocellular carcinomas observed in the long-term studies with BHT. Exposure of adults to BHT is unlikely to exceed the newly derived ADI at the mean and at the 95th percentile. For exposure of children to BHT from its use as food additive, the Panel noted that it is also unlikely that this ADI is exceeded at the mean, but is exceeded for some European countries (Finland, The Netherlands) at the 95th percentile.<sup>32</sup> Genotoxic and carcinogenic impurities – margin of exposure approach

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<sup>30</sup> Regulation (EU) No 231/2012 of 9 March 2012 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:083:0001:0295:EN:PDF> (accessed 21.06.12)

<sup>31</sup> BMDL10 - benchmark dose lower confidence limit 10% see Toxicology section below p 37

<sup>32</sup> EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the reevaluation of Butylated hydroxytoluene BHT (E 321) as a food additive. EFSA Journal 2012;10(3):2588. [43 pp.]

For substances that are both genotoxic and carcinogenic, in theory, no safe concentration of intake can be given. EFSA (The Panel on Food Additives and Nutrient Sources Added to Food, ANS Panel) has used the margin of exposure, MoE, approach (see below – Regulation, Toxicology) in some of its scientific opinions to judge the safety of impurities, and is proposing in its new draft guidance on submission for food additive evaluations use of the MoE approach for assessing the risk from impurities in the additive which are genotoxic and carcinogenic. The ANS Panel asked the Scientific Committee for guidance on the acceptability and validity of such an approach. The Scientific Committee recognised that this is an important problem. Analytical methodology is continually improving, and an increasing number of impurities, including some which are both genotoxic and carcinogenic, can be detected at low levels in, for example, food/feed additives or food contact materials. The Scientific Committee is of the opinion that the MOE approach can be applied to impurities which are both genotoxic and carcinogenic, irrespective of their origin. The Committee notes that the wider application of the MOE would raise some scientific and risk management issues concerning interpretation. In general a MoE of 10,000 or higher, if it is based on the BMDL10 from an animal carcinogenicity study, would be of low concern from a public health point of view and might be reasonably considered as a low priority for risk management actions. However, such a judgment is ultimately a matter for the risk managers on a case by case basis. Moreover an MOE of that magnitude should not preclude the application of risk management measures to reduce human exposure. However, there is at present no international consensus on banding of MOEs and corresponding descriptive terminology and further discussions among stakeholders are recommended.<sup>33</sup>

## Lycopene

The use of lycopene as a food colour has been restricted see above, Regulation 1129/2011.

## Food Contact Materials

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food established an EU list of monomers, other starting substances and additives which may be used in the manufacture of plastic materials and articles. Recently EFSA issued favourable scientific evaluations for additional substances and amendments to the current list. The CAS number of FCM substance number 797 polyester of adipic acid with 1,3-butanediol, 1,2- propanediol and 2-ethyl-1-hexanol also needed to be corrected. These changes were put into effect by Commission Regulation (EU) No 1282/2011 of 28 November 2011.<sup>34</sup>

## Bisphenol A

In March EFSA published a literature survey by the University of Parma on the most relevant toxicology papers on bisphenol A which will be assessed by EFSA's experts.<sup>35</sup>

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doi:10.2903/j.efsa.2012.2588. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2588.htm> (Accessed 04.07.12)

<sup>33</sup> EFSA Scientific Committee; Scientific Opinion on the applicability of the Margin of Exposure approach for the safety assessment of impurities which are both genotoxic and carcinogenic in substances added to food/feed. EFSA Journal 2012;10(3):2578. [5 pp.] doi:10.2903/j.efsa.2012.2578. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2578.htm> (accessed 03 07 12)

<sup>34</sup> Commission Regulation (EU) No 1282/2011 of 28 November 2011 amending and correcting Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:328:0022:0029:EN:PDF> accessed 23.01.12.

<sup>35</sup> University of Parma, Bisphenol A Literature Survey 2012, <http://www.efsa.europa.eu/en/supporting/pub/252e.htm> (accessed 10.07.12)

## Oxygen absorbers

Also of interest in March was an EFSA scientific opinion of on active substances activated carbon, water, iron powder, calcined kaolin, sulphur and sodium chloride used in mixtures packed into sachets for absorbing oxygen from the food environment. All substances of the oxygen absorber formulations have been evaluated and approved for use as additives in plastic food contact materials and/or as food supplements (sodium chloride). The CEF Panel concluded that their use does not raise a safety concern.<sup>36</sup>

EFSA also dealt with palladium as an oxygen absorber concluding that there is no safety concern in the circumstances of use. The opinion covered palladium acetate reduced by sodium borohydride to palladium in plastic during the manufacturing process used as an oxygen absorbing system in food contact materials. The CEF Panel considers that palladium is non genotoxic and a low exposure to palladium resulting from a concentration up to 0.05 mg/kg food is not of toxicological concern. In addition, the CEF Panel used the tolerable upper intake level (UL) of 0.16 mg boron/kg bw per day equivalent to 10 mg boron/person per day in adults established by EFSA in 2004, instead of the previously derived TDI of 0.1 mg boron/kg bw. Migration of palladium into food was not detectable (detection limit = 0.0005 mg/kg) while the migration of boron into food was up to 0.09 mg/kg. Based on the default assumption for food contact materials that an adult may consume daily up to 1 kg of food in contact with food contact materials containing boron, the migration of 0.09 mg/kg food would correspond to an intake of 0.09 mg boron/adult/day which is 111 times lower than the UL.<sup>37</sup>

## Sodium saccharin

EFSA in March 2012 issued a risk assessment of the additive 1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt (saccharin, sodium salt, CAS No 128-44-9 and FCM Substance No 902), for use as a nucleating agent up to 0.1% w/w in polyesters. The substance was evaluated by the SCF in 1995 which concluded that it is appropriate to set a full ADI for sodium saccharin of 0-5 mg/kg bw. Under the present evaluation, the CEF Panel concluded that the use of the substance, as additive in polyesters, is not of safety concern for the consumer but should comply with the specific purity criteria as set in Directive 2008/60/EC.<sup>38</sup>

## ***Natural Mineral and other Bottled Waters***

No further legislative developments this period. However, EFSA issued an opinion on the minimum hygiene criteria to be applied to clean seawater and on the public health risks and hygiene criteria for bottled seawater intended for domestic use. The concentration of chemicals in bottled seawater should comply with the standards laid down in Council Directive 98/83/EC on the quality of water intended for human consumption. It is recommended to use

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<sup>36</sup> EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF); Scientific Opinion on the safety evaluation of the active substances, activated carbon, water, iron powder, kaolin calcined, sulphur and sodium chloride for use as active component in food contact materials. EFSA Journal 2012;10(3):2643. [12 pp.] doi:10.2903/j.efsa.2012.2643. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2643.htm> (Accessed 04.07.12)

<sup>37</sup> EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF); Scientific Opinion on the safety evaluation of the active substances, sodium borohydride and palladium acetate for use in active food contact materials. EFSA Journal 2012;10(3):2642. [15 pp.] doi:10.2903/j.efsa.2012.2642. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2642.htm> (Accessed 04.07.12)

<sup>38</sup> EFSA Panel on Food Contact Materials, Flavourings, Enzymes and Processing Aids; Scientific Opinion on the safety evaluation of the substance, 1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt, CAS No. 128-44-9, for use in food contact materials. EFSA Journal 2012;10(3):2640. [9 pp.] doi:10.2903/j.efsa.2012.2640. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2640.htm> (Accessed 04.07.12)

ultraviolet (UV) or other physical methods as the preferred disinfection process to prevent the formation of hazardous disinfection by-products such as bromate and trihalomethanes.<sup>39</sup>

## **Pesticides**

Commission Regulation (EU) No 270/2012 of 26 March 2012<sup>40</sup> 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 amidosulfuron, azoxystrobin, bentazone, bixafen, cyproconazole, fluopyram, imazapic, malathion, propiconazole and spinosad in or on certain products .

EFSA, in March 2012 issued guidance on a Standard Sample Description for the reporting of data on the control of pesticide residues in food and feed according to Regulation (EC) No 396/2005.<sup>41</sup>

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 programme 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. The activities of the Networks of the Pesticides Unit in 2011 were reported in January 2012.<sup>42</sup>

## **Veterinary Residues**

Revised MRLs for altrenogest, closantel, lasalocid, methylprednisolone, monepantel, nitroxinil octenidine dihydrochloride, pegylated bovine granulocyte colony stimulating factor, phenoxymethylpenicillin and triclabendazole were authorised in Q1 2012 by a set of Regulations amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

For further information see

[http://ec.europa.eu/food/food/chemicalsafety/residues/index\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/residues/index_en.htm)

A Report on the results from the 2010 monitoring of veterinary medicinal product residues and other substances in live animals and animal products was issued by EFSA in March 2012.<sup>43</sup>

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<sup>39</sup> EFSA Panel on Biological Hazards (BIOHAZ) and EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on the minimum hygiene criteria to be applied to clean seawater and on the public health risks and hygiene criteria for bottled seawater intended for domestic use. EFSA Journal 2012;10(3):2613. [85 pp.] doi:10.2903/j.efsa.2012.2613. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2613.htm> (accessed 03.07.12)

<sup>40</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:089:0005:0063:EN:PDF>

<sup>41</sup> [Guidance of EFSA – Standard Sample Description](#) (Noted but not seen)

<sup>42</sup> European Food Safety Authority; The activities of the Networks of the Pesticides Unit in 2011. Supporting Publications 2012:EN-229. [10 pp.]. Available at <http://www.efsa.europa.eu/en/supporting/pub/229e.htm> (accessed 10.07.12)

<sup>43</sup> European Food Safety Authority; Report for 2010 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products. Supporting Publications 2012:212. [65 pp.]. Available at <http://www.efsa.europa.eu/en/supporting/pub/212e.htm> (Accessed 04.07.12)

## **Nanomaterials**

See definition of engineered nanomaterial and labelling provisions in the new Food Information Regulation.

### **Titanium nitride nanoparticles**

In March 2012 EFSA published an opinion on the safety evaluation of titanium nitride, nanoparticles in connection with a request for an extension of their use in thermoformed PET sheets/films in addition to the use in PET bottles previously evaluated by the EFSA in 2008. The conclusions were that no migration of the substance into food is expected and therefore no exposure of the consumer via food is expected. Based on this, the CEF Panel concluded that there is no safety concern for the consumer if the substance is used up to 20 mg/kg in only PET plastics intended for contact with all types of foodstuffs under conditions of any duration of time and at temperatures up to and including hot-fill.<sup>44</sup>

### **EFSA Nano Network**

The EFSA Nano Network published its first annual report in February 2012. The Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed (“Nano Network”) was launched in 2011. The network had its first annual meeting in February 2011. The network is currently composed of representatives from 21 Member States, Norway and from EU Candidate countries as observers, 5 EFSA Scientific Committee, Panel or Working Group Experts and 3 EFSA scientific staff members of the SCOM unit. The report details the activities of the first annual meeting in February 2011 including EFSA activities and activities at the Joint Research Centre. The JRC has produced a repository composed of 25 different nanomaterials and IRMM has made available a certified silicon dioxide for specific size measurements. The JRC is also hosting an IT platform called “Nanohub” and is involved in the REACH implementation as members of the REACH implementation steering group which is led by DG ENV. The need for suitable measuring methods and validated tests methods, for both in vitro and in vivo, was reiterated by the participants. Member States supported the importance of thorough identification and characterisation of nanomaterials, and noted that this information may currently be difficult to generate for some nanomaterials, especially in complex matrices. The UK FSA presented the background and the ongoing activities of its Nanotechnologies and the Food Discussion Group regularly published on the FSA website. The Federal Institute for Risk Assessment (BfR) presented ongoing activities in Germany. A list of national participants was given. David Gott is the FSA representative.<sup>45</sup>

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<sup>44</sup> EFSA Panel on Food Contact Materials, Flavourings, Enzymes and Processing Aids; Scientific Opinion on the safety evaluation of the substance, titanium nitride, nanoparticles, for use in food contact materials. EFSA Journal 2012;10(3):2641. [8 pp.] doi:10.2903/j.efsa.2012.2641. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2641.htm> (accessed 04.07.12)

<sup>45</sup> European Food Safety Authority; EFSA Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed. Supporting Publications 2012:EN-246. [10 pp.]. Available at <http://www.efsa.europa.eu/en/supporting/pub/246e.htm> (accessed 10.07.12)

## Food Hygiene

### Antimicrobial resistance

In March 2012 EFSA published 2010 antimicrobial resistance data on zoonotic and indicator bacteria submitted by 26 European Union Member States. The data, jointly analysed by EFSA and the European Centre for Disease Prevention and Control *Salmonella* and *Campylobacter* from humans, food and animals, and in indicator *Escherichia coli* and enterococci from animals and food. Some data on methicillin-resistant *Staphylococcus aureus* in animals and food were also included. No major changes in resistance in monitored bacteria were observed compared with previous years. Resistance was commonly found in isolates from humans, animals and food, although disparities in resistance were frequently observed between Member States. High resistance levels were recorded to ampicillin, tetracyclines and sulfonamides in *Salmonella* isolates from humans, whereas resistance to third-generation cephalosporins and fluoroquinolones remained low. In *Salmonella* and indicator *E. coli* isolates from fowl, pigs, cattle and meat thereof, resistance to tetracyclines, ampicillin and sulfonamides was also commonly detected, whereas resistance to third-generation cephalosporins was low. Moderate to high levels of ciprofloxacin (a fluoroquinolone) resistance were observed in *Salmonella* isolates from turkeys, fowl and broiler meat. In *Campylobacter* isolates from human cases, resistance to ampicillin, ciprofloxacin, nalidixic acid and tetracyclines was high, while resistance to erythromycin was recorded at low to moderate levels. High resistance to ciprofloxacin, nalidixic acid and tetracyclines was also observed in *Campylobacter* isolates from fowl, broiler meat, pigs and cattle, whereas much lower levels were observed for erythromycin and gentamicin. Among the indicator enterococci isolates from animals and food, resistance to tetracyclines and erythromycin was commonly detected. Methicillin-resistant *Staphylococcus aureus* was detected in some animal species and food of animal origin.<sup>46</sup>

### Cetylpyridinium chloride removal of microbial contamination of raw poultry products

EFSA published in March an opinion on an application for potential approval of Cecure® for the removal of microbial surface contamination of raw poultry products. Cecure® consists of aqueous cetylpyridinium chloride (CPC) at a concentration not to exceed 1 % and propylene glycol (PG), and is applied by drenching on whole chicken carcasses and recycled after use. Based on the available evidence, EFSA had no concern for genotoxicity of CPC and no safety concerns for humans from the proposed use. Although the proposed drench appeared to be efficacious in reducing contamination with pathogenic microorganisms on fresh broiler carcasses, data about the potential emergence and selection of isolates with reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials linked to the use of CPC were not provided or not considered sufficient for the assessment. Based on the available limited data, the intended use of CPC in poultry slaughterhouses would pose risks for the environmental compartments surface water, sediment and soil. No risks for the function of sewage treatment plants are expected and there are no safety concerns regarding secondary poisoning for birds and mammals, and for humans indirectly exposed via the environment.<sup>47</sup>

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<sup>46</sup> European Food Safety Authority and European Centre for Disease Prevention and Control; The European Union Summary Report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2010. EFSA Journal 2012; 10(3):2598 [233 pp.] doi:10.2903/j.efsa.2012.2598. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2598.htm> (Accessed 04.07.12)

<sup>47</sup> EFSA Panel on Biological Hazards (BIOHAZ) and Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on the evaluation of the safety and efficacy of Cecure® for the removal of microbial surface contamination of raw poultry products. EFSA Journal 2012;10(3):2612. [66 pp.] doi:10.2903/j.efsa.2012.2612. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2612.htm> (accessed 04.07.12)

## Norovirus in oysters

Norovirus, NoV, is highly infectious, and there is no threshold infectivity limit for NoV detected by PCR. In a scientific opinion on NoV in oysters EFSA examined methods, limits and control options finding that the most effective public health measure to control human NoV infection from oyster consumption is to produce oysters from areas which are not faecally contaminated, particularly given the ineffectiveness of current depuration and relaying procedures.<sup>48</sup>

## Zoonoses and food-borne outbreaks

EFSA and the European Centre for Disease Prevention and Control published in March 2012 the 2010 data on the occurrence of zoonoses and food-borne outbreaks submitted by 27 European Union Member States. The decreasing trend in salmonellosis cases in humans continued. Most Member States met their *Salmonella* reduction targets for poultry, and *Salmonella* is declining in these populations. In foodstuffs, *Salmonella* was most often detected in fresh broiler and turkey meat. Campylobacteriosis was the most commonly reported zoonosis, and *Campylobacter* was most often detected in fresh broiler meat. The number of human listeriosis cases decreased slightly with *Listeria* seldom detected above the legal safety limit from ready-to-eat foods at retail. Confirmed verotoxigenic *Escherichia coli* (VTEC) infections has been increasing since 2008. VTEC was also observed in food and animals. The numbers of human yersiniosis cases have been decreasing in recent years. *Yersinia enterocolitica* was isolated also from pig meat and pigs; 133 cases of *Mycobacterium bovis* and 356 cases of brucellosis in humans were also reported. The prevalence of bovine tuberculosis in cattle increased, and the prevalence of brucellosis decreased in cattle, sheep and goat populations. Trichinellosis and echinococcosis caused 223 and 750 confirmed human cases, respectively. These parasites were mainly detected in wildlife. The number of Q fever cases in humans decreased to 1,414. In animals Q fever was found in domestic ruminants. There were two human cases of rabies in 2010 and the number of rabies cases in animals slightly increased. Most of the 5,262 reported food-borne outbreaks were caused by *Salmonella*, viruses, *Campylobacter* and bacterial toxins and the main food sources were eggs, mixed or buffet meals and vegetables.<sup>49</sup>

## Schmallenberg virus (SBV)

In autumn 2011 a previously unknown virus, provisionally named as "Schmallenberg" virus (SBV), was reported in ruminants (cattle, sheep and goats) from Germany, The Netherlands, Belgium, the United Kingdom and France. In January 2012, the European Commission requested scientific assistance from EFSA and a preliminary analysis of the likely epidemiological scenarios that could be observed in the next months was requested, based on the existing knowledge of viruses of the Simbu virus serogroup and other vector borne epidemics in the region. A report (February 2012) provides likely epidemiological scenarios and data needed to improve the understanding of the disease spread and impact of SBV.

The report mainly focuses on animal health aspects. Current knowledge suggests that it is unlikely that SBV can cause disease in humans. No additional information has since become

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<sup>48</sup> EFSA Panel on Biological Hazards (BIOHAZ); Norovirus (NoV) in oysters: methods, limits and control options. EFSA Journal 2012;10(1):2500. [39 pp.] doi:10.2903/j.efsa.2012.2500. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2500.htm> (accessed 10.07.12)

<sup>49</sup> European Food Safety Authority, European Centre for Disease Prevention and Control; The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2010; EFSA Journal 2012; 10(3):2597. [442pp.] doi:10.2903/j.efsa.2012.2597. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2597.htm> (Accessed 04.07.12)



available to invalidate this assessment. However, EFSA and ECDC are closely monitoring the situation in order to address public health concerns should these arise.<sup>50</sup>

### ***Transmissible spongiform encephalopathies (BSE-TSEs)***

In January 2012 the 2011 annual report of the EFSA Scientific Network on BSE-TSEs was published.<sup>51</sup>

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<sup>50</sup> European Food Safety Authority; "Schmallenberg" virus: likely epidemiological scenarios and data needs. Supporting Publications 2012:EN-241. [31 pp.]. Available at <http://www.efsa.europa.eu/en/supporting/pub/241e.htm> (accessed 10.07.12)

<sup>51</sup> European Food Safety Authority; Annual report of the Scientific Network on BSE-TSE. Supporting Publications 2012:EN-221. [7 pp.]. Available at <http://www.efsa.europa.eu/en/supporting/pub/221e.htm> (accessed 10.07.12)

## Consumer Choice and Prevention of Fraud

### **Composition and Labelling**

#### **Use by date – case law**

In a case before Aikens LJ and Maddison J in a Divisional Court appeal by way of case stated by the prosecuting authority, Torfaen County Borough Council, it was held that the fact that food was labelled with a “use by” date would be *prima facie* evidence that the food required to be so labelled in accordance with regulations 2, 4 and 5 of the Food Labelling Regulations 1996 and would place an evidential burden on the defendant to demonstrate that the label had not, in fact, been required. If the food was subsequently frozen, it did not cease to require to have a “use by” label attached to it. If such food was subsequently sold, within the definition in regulation 2, after the “use by” date, the offence under regulation 44(1)(d) would be made out.<sup>52</sup>

#### **New EU Food Labelling Regulation Made**

Regulation 1169/2011<sup>53</sup> on the provision of food information to consumers has been in gestation since 2008 and is a once in a generation major change to the way in which food is labelled. The principal changes include:

- A requirement for nutrition information on processed foods;
- Origin labelling of fresh meat from pigs, sheep, goats and poultry;
- Certain allergens must be highlighted in the list of ingredients and information on allergens also cover non pre-packed foods including those sold in restaurants and cafés.
- More developed legibility requirements, i.e. minimum size of text;

The new rules will apply from 13 December 2014. The obligation to provide nutrition information will apply from 13 December 2016.

The new Regulation sets overarching principles for food labelling law and principles against which future labelling law should, when & if necessary, develop.

Two previous Directives, 2000/13/EC (labelling, presentation and advertising of foodstuffs) and 90/496/EEC (nutrition labelling for foodstuffs) are combined and amalgamated with other labelling law such as that on caffeine, quinine and phytosterols/stanols. Hence there is much that will be familiar to those already dealing with food labelling. For example most of the

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<sup>52</sup> Torfaen County Borough Council v Douglas Willis Ltd, [2012] EWHC 296 (Admin); [2012] WLR (D) 37 Reported by: Giovanni D’Avola, Barrister, available at <http://cases.iclr.co.uk/Subscr/search.aspx?path=WLR%20Dailies/WLRD%202011/wlrd2012-037> (accessed 10.07.12)

<sup>53</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, available at: <http://eur-lex.europa.eu/Notice.do?val=626987:cs&lang=en&list=626987:cs.&pos=1&page=1&nbl=1&pgs=10&hwords=> accessed 20.01.12.

mandatory labelling required by Article 9 is not new and many previous requirements are carried over into the new Regulation.

Expanding on the above novel (though long signalled) changes we note that a newly mandatory nutrition declaration is required disclosing the energy value and the amounts of fat, saturates, carbohydrate, sugars, protein and salt. The content of the mandatory nutrition declaration may be supplemented with declarations of one or more of: mono-unsaturates, polyunsaturates, polyols, starch, or fibre. Regulations (EC) No 1924/2006 and (EC) No 1925/2006 will need to be amended in relation to addition of vitamins and minerals and other substances to foods.

Also new is a requirement to indicate the country of origin or place of provenance where failure to indicate this might mislead the consumer. This is covered in detail in Article 26. Applying to pigs, sheep, goats and poultry (beef already being dealt with by 1760/2000), concrete proposals to implement are expected from the Commission by the end of 2013. Taking proportionality into account and the administrative burden for food business operators and enforcement authorities the Commission must also explore the possibility of extending mandatory origin labelling for other foods.

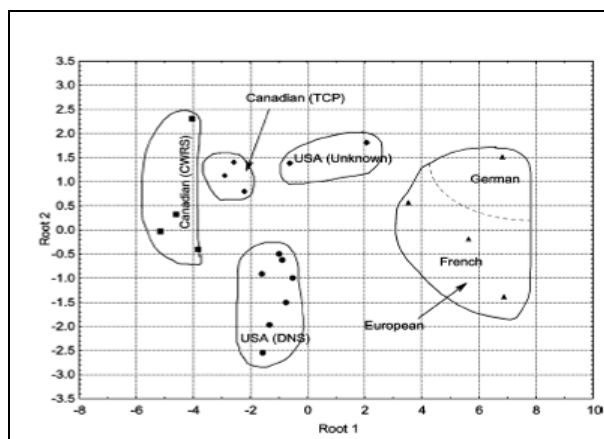
For beverages containing more than 1.2 % by volume of alcohol, the actual alcoholic strength by volume is required and the Commission is invited to produce a report within 3 years of the entry into force of this Regulation concerning the application of the requirements to provide information on ingredients and nutrition information to alcoholic beverages

Developments on engineered nanomaterials are recognised with a definition and a requirement that all such ingredients must be clearly indicated in the list of ingredients by way of the name followed by the word 'nano' in brackets.

In addition, a study is proposed on the opportunity to provide consumers with the relevant information on the pre slaughter stunning of animals in the context of a future EU strategy for the protection and welfare of animals.

Clearly some of the above new requirements, particularly those on country of origin and nanomaterials, although only coming into force after some years, will stretch analytical verification and testing systems.

Much work has already been done. Geographic provenance can be investigated by looking at how trace elements differ when ingested by an animal from the water it drinks and from the soil where its feed is grown using multi-element inductively coupled plasma mass spectrometry, ICP-MS. ICP-MS can measure the amounts of up to 20 elements and their isotopes simultaneously. Figure 1 shows differentiation of wheat crop geographical origin in an early paper by RHM and LGC scientists based on work on carbon isotopes and other trace elements.

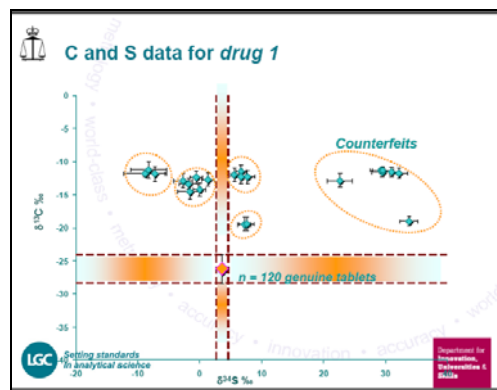


**Fig 1. Wheat crop geographical origin (Branch *et al.*, 2002, JAAS, 18, 17 – 22).**

Isotope ratios change from place to place on the globe due to natural processes. Examples include:

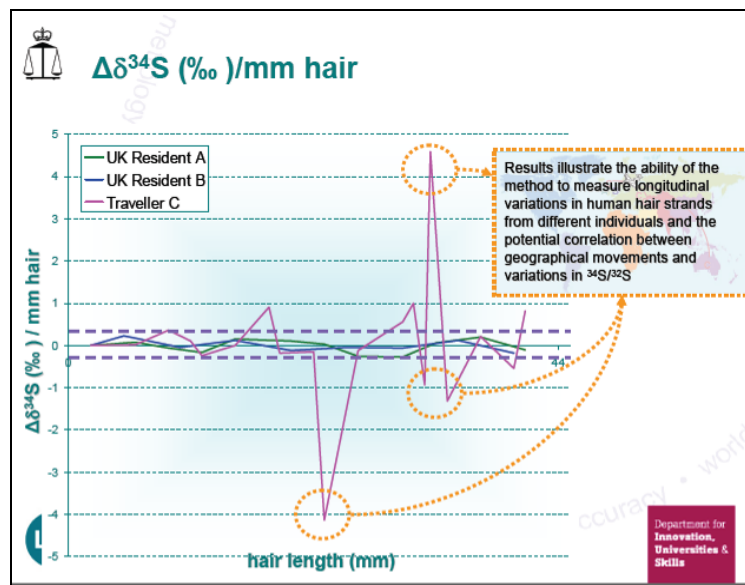
- Evaporation and rainfall fractionate heavier hydrogen and oxygen isotopes, which remain in the liquid phase;
- Carbon and nitrogen isotopes fractionate in different plants;
- Geological factors and sea-spray deposition influence sulphur and strontium isotopes.

Some examples of where these effects can be used to pin point geographical origin include work by Fera scientists to differentiate beef across Britain, and between Britain and Brazil. At LGC such work has enabled tracking of counterfeit medicines, see Figure 2, applying absolute measurements by multicollector ICP-MS and experience gained in the Forensic Isotope Ratio Mass Spectrometry Network (FIRMS) will be valuable.



**Fig. 2 Tracing counterfeit medicines by sulphur and carbon isotope ratios, LGC presentation, presented at the Government Chemist’s Conference 2009.**

Measurements at LGC of sulphur isotope ratios along the length of a hair have demonstrated that it is possible to identify global travelling, see figure 3.



**Fig. 3 Proof of foreign residence by hair analysis LGC presentation, presented at the Government Chemist’s Conference 2009.**

Thus by a combination of approaches much can be done scientifically to probe and police geographic origin of high value foods. While it remains to be seen if the OCL system will be funded to deploy such techniques and recognising that their use in court has been minimal,

the GC should consider further work, perhaps scenario planning to explore what techniques may need to be deployed in the event of a dispute or query arising from the new Food Information regulation.

## Traceability

Lot markings (in certain cases the date of minimum durability or 'use by' date) are required for traceability. Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs has been substantially amended several times. In the interests of clarity and rationality that Directive has been codified and substantially replaced by Directive 2011/91/EU of 13 December 2011.<sup>54</sup>

## Wine Regulations

These Regulations<sup>55</sup> enforce in the United Kingdom "the European Regulations" defined in regulation 2 as:

- [Council Regulation \(EEC\) No 1601/91](#) laying down general rules on the definition, description and presentation of aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails,
- [Council Regulation \(EC\) No 1234/2007](#) establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) relating to wine,
- [Commission Regulation \(EC\) No 555/2008](#) laying down detailed rules for implementing Council Regulation (EC) No 479/2008 on the common organisation of the market in wine as regards support programmes, trade with third countries, production potential and on controls in the wine sector,
- [Commission Regulation \(EC\) No 436/2009](#) laying down detailed rules for the application of Council Regulation (EC) No 479/2008 as regards the vineyard register, compulsory declarations and the gathering of information to monitor the wine market, the documents accompanying consignments of wine products and the wine sector registers to be kept;
- [Commission Regulation \(EC\) No 606/2009](#) laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions, and
- [Commission Regulation \(EC\) No 607/2009](#) of 14 July 2009 laying down certain detailed rules for the implementation of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products.

Regulation 3 sets out the enforcement authority for the purposes of the European Regulations and regulation 4 sets out the competent authority. Regulation 5 requires those who plant more than 0.1ha of vines and are not already registered to register with the Food Standards Agency. Regulation 6 and Schedules 1 and 2 set out the requirements for protected geographical indications and protected designations of origin. Regulations 8 to 17 set out enforcement related provision. In particular, regulation 14 creates offences in relation to breach of the European Regulations and regulation 15 sets out the penalties on conviction. Regulation 18 requires the Secretary of State to review these Regulations and publish a report at a maximum interval of every five years.

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<sup>54</sup> Directive 2011/91/EU of the European Parliament and of the Council of 13 December 2011 on indications or marks identifying the lot to which a foodstuff belongs <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:334:0001:0005:EN:PDF> accessed 23.01.12.

<sup>55</sup> The Wine Regulations 2011 <http://www.legislation.gov.uk/ukxi/2011/2936/made/data.pdf> accessed 23.01.12.

## Organic Wine

Commission Implementing Regulation (EU) No 203/2012 of 8 March 2012 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007, as regards detailed rules on organic wine was made.<sup>56</sup>

Regulation (EC) No 834/2007 lays down basic requirements with regard to organic production of processed food with detailed rules in Commission Regulation (EC) No 889/2008 of 5 September 2008. Following a scientific study the Commission has recognised that processing of organic wine requires the use of certain additives or processing aids under well-defined conditions. A range of additives including edible gelatine, plant proteins from wheat or peas, isinglass, egg white albumin, tannins, casein, and pectolytic enzymes are permitted for clarification. (See Annex in the regulation for full list). Practices such as heat treatment, filtration, reverse osmosis and the use of ion exchange resins widely used in food processing are also available and although they may have an effect on the true nature of organic wine, at present no alternative techniques are available to replace them. Hence they should be available to organic wine-makers, but their use should be restricted and, except for filtration, reassessed in the future. However, oenological practices such as concentration by cooling, dealcoholisation, the elimination of sulphur dioxide by physical process, electrodialysis and the use of cation exchangers were regarded as potentially misleading and are excluded in the making of organic wine. Organic wine producers can reduce sulphur dioxide concentrations and lower maxima than in non-organic wines have been set depending e.g. on sugar content. There are exceptions for extreme weather conditions where supplementary sulphites for stability are allowed.

## Fish Parasites

Previous reports have included items on fish parasites (e.g. cod worms) and Part D of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 provides that food business operators must ensure that certain fishery products, including those to be consumed raw or almost raw, undergo a freezing treatment to kill viable parasites that may represent a risk to the health of the consumer. These rules have been relaxed for wild catches from areas known not to present a risk and for farmed Atlantic salmon as their feed and rearing mitigate against development of parasitic infection.<sup>57</sup>

## Novel Foods

Two novel foods were authorised in November 2011. Commission Implementing Decisions of 24 November 2011 authorised flavonoids from *Glycyrrhiza glabra* L. (Glavonoid, see previous quarter's report)<sup>58</sup> and yeast beta-glucans<sup>59</sup> as novel food ingredients under Regulation (EC)

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<sup>56</sup> Commission Implementing Regulation (EU) No 203/2012 of 8 March 2012 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:071:0042:0047:EN:PDF> (accessed 19.06.12)

<sup>57</sup> Commission Regulation (EU) No 1276/2011 of 8 December 2011 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the treatment to kill viable parasites in fishery products for human consumption <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:327:0039:0041:EN:PDF>

<sup>58</sup> Commission Implementing Decision authorising the placing on the market of flavonoids from *Glycyrrhiza glabra* L. as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council, (notified under document C(2011) 8362), (Only the Dutch and the French texts are authentic), (2011/761/EU), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:313:0037:0040:EN:PDF>

<sup>59</sup> Commission Implementing Decision authorising the placing on the market of yeast beta-glucans as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document C(2011) 8527)

No 258/97 (notified under documents C(2011) 8362, and C(2011) 8527) . A novel chewing gum base was also authorised as a novel food.<sup>60</sup>

## **Food Irradiation**

No further legislative developments this quarter

## **GMOs**

On 10 February 2012, pursuant to Regulation (EC) No 1829/2003, four routine decisions<sup>61</sup> were made authorising the sale of genetically modified soybean:

| GMO                             | Document Number |
|---------------------------------|-----------------|
| Soybean A5547-127 (ACS-GMØØ6-4) | C(2012) 691     |
| Soybean 40-3-2 (MON-Ø4Ø32-6)    | C(2012) 700     |
| Soybean MON 87701 (MON-877Ø1-2) | C(2012) 701     |
| Soybean 356043 (DP-356Ø43-5)    | C(2012) 702     |

## **Emergency measures on unauthorised GM rice in rice products from China**

Less routinely further emergency measures regarding unauthorised genetically modified rice in rice products originating from China were made by Commission Implementing Decision 2011/884/EU.<sup>62</sup>

In September 2006, rice products from China, contaminated with the unauthorised genetically modified rice Bt 63, were discovered in the United Kingdom, France and Germany and were notified to RASFF. This was followed by other alerts and Commission Decision 2008/289/EC was adopted which introduced emergency measures regarding the unauthorised GMO Bt 63 in rice products. The emergency measures included (a) an analytical report demonstrating that the consignment of rice products was not contaminated and (b) random sampling and analysis at the port of entry. In March 2010, Germany notified a RASFF on the presence of new rice varieties carrying unauthorised genetic elements encoding insect resistance which had characteristics similar to the GMO Kefeng 6. Subsequently, several additional similar alerts were notified, which in addition to Kefeng 6, also included the presence of another insect resistant rice line which contained genetic elements similar to the GMO Kemingdao 1 (KMD1). Kefeng 6 and KMD1 are not authorised either in the EU or China.

FVO inspections in 2008 and 2010 in China failed to provide reassurance and since no genetically modified rice products are authorised in the EU the scope of measures provided for by Decision 2008/289/EC, which is limited to genetically modified rice Bt 63, were broadened, by a Decision of 22 December 2011, to all genetically modified organisms found

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(Only the English text is authentic) (2011/762/EU) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:313:0041:0044:EN:PDF> accessed 23.01.12.

<sup>60</sup> Commission Implementing Decision of 21 December 2011 authorising the placing on the market of a novel chewing gum base as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document C(2011) 9680) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:343:0121:0122:EN:PDF>

<sup>61</sup> See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:040:0010:0013:EN:PDF>  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:040:0014:0017:EN:PDF>  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:040:0018:0021:EN:PDF>  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:040:0022:0025:EN:PDF>

Noted but not accessed

<sup>62</sup> Commission Implementing Decision of 22 December 2011 on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:343:0140:0148:EN:PDF> accessed 23.01.12.

in rice products originating in or consigned from China. The list in the annex to the decision is comprehensive, including for example, pasta, infant food and muesli-type food based on unroasted cereal grains.

The obligation to provide an analytical report on sampling and analysis demonstrating the absence of genetically modified rice events, established by Decision 2008/289/EC, was maintained. However, MS controls were bolstered through 100% frequency of sampling and analysis of consignments of rice products originating from China, and the introduction of the obligation for food and feed operators to give prior notification of the estimated date, time and place of the physical arrival of the consignment.

A common protocol for sampling and analysis was defined in Annex II to the decision.

All food and feed products which have rice listed as an ingredient are targeted. Food business operators are allowed however to issue a simple declaration when a product does not contain, consist or is produced from rice, thus avoiding the compulsory analysis and certification.

The Decision entered into force on 12<sup>th</sup> January 2012 and will be reviewed. Decision 2008/289/EC is repealed but references to the repealed Decision shall be construed as references to this Decision. The decision was brought into effect in the four countries of the UK by a set of regulations of which the English version was the Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2012.<sup>63</sup> These Regulations, which came into force on 12th January 2012, amend the Specified Products from China (Restriction on First Placing on the Market) (England) Regulations 2008 (S.I.2008/1079) (“the 2008 Regulations”). They amend the 2008 Regulations by:

- the usual changes in definitions;
- amending regulation 3(1), by imposing conditions under which specified products (rice and rice products originating in or consigned from China) may be placed on the market(regulation 2(3));
- omitting regulation 4, which required operators to notify the Food Standards Agency of certain test results (regulation 2(4));
- amending regulation 5(4), which identifies the provisions of the Commission Decision that an enforcement officer of a feed or food authority must ensure are observed(regulation 2(5));
- inserting as new regulation 7 a provision to implement the requirement in Article 8 of the Commission Decision that all costs resulting from the official controls and from any non-compliance must be borne by the food or feed business operator concerned(regulation 2(7)); and
- inserting as new regulation 8 a provision implementing the transitional arrangements contained in Article 9 of the Commission Decision (regulation 2(7)).

Similar Regulations were made in Scotland,<sup>64</sup> Wales<sup>65</sup> and Northern Ireland<sup>66</sup>.

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<sup>63</sup> The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2012 <http://www.legislation.gov.uk/uksi/2012/47/made/data.pdf> (accessed 31.05.12)

<sup>64</sup> The Specified Products from China (Restriction on First Placing on the Market) (Scotland) Amendment Regulations 2012 <http://www.legislation.gov.uk/ssi/2012/3/made/data.pdf>

<sup>65</sup> The Specified Products from China (Restriction on First Placing on the Market) (Wales) (Amendment) Regulations 2012 <http://www.legislation.gov.uk/wsi/2012/64/made/data.pdf>

<sup>66</sup> The Specified Products from China (Restriction on First Placing on the Market) (Amendment) Regulations (Northern Ireland) 2012 <http://www.legislation.gov.uk/nisr/2012/3/made/data.pdf>



## GM potato EH92-527-1

On 2 March 2010 Commission adopted a decision authorising the placing on the market of GM potato EH92-527-1 for cultivation and industrial starch production. However in June 2010, Austria notified the Commission of a national measure prohibiting the placing on the market of GM potato EH92-527-1 for cultivation purposes in Austria and provided scientific support for this decision. In May 2011 EFSA was asked by the Commission to assess the scientific information submitted by the Austrian Authorities in the context of a safeguard clause invoked under Article 23 of Directive 2001/18/EC. In March 2012 EFSA published a statement on GM potato EH92-527-1 from its GMO Panel concluded that for cultivation purposes in Austria no grounds exist to date that would lead to reconsideration of its opinion on GM potato EH92-527-1.<sup>67</sup>

## Guidance for the risk assessment

In January 2012 EFSA published guidance for the risk assessment of food and feed containing, consisting of or produced from genetically modified (GM) animals, as well as for the health and welfare assessment of these animals, within the framework of Regulation (EC) No 1829/2003 on GM food and feed.<sup>68</sup>

## Cisgenesis and intragenesis

New breeding and genetic modification techniques have evolved and in some instances it is unclear whether they give rise to GMOs pursuant to EU Legislation. At the request of the Competent Authorities (CA) under Directive 2001/18/EC, a New Techniques Working Group (NTWG) was established in October 2007 to analyse a non-exhaustive list of techniques for which it is unclear whether they would result in a GMO as defined under Directive 2001/18/EC or Directive 2009/41/EC respectively. An initial list of eight techniques was proposed by the CA for consideration by the NTWG. In February 2012 EFSA published a scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. The report helpfully gives definitions. "Cisgenesis is the genetic modification of a recipient organism with a gene from a crossable, sexually compatible, organism (same species or closely related species). This gene includes its introns and is flanked by its *native* promoter and terminator in the normal sense orientation. Cisgenic plants can harbour one or more cisgenes, but they do not contain any parts of transgenes or inserted foreign sequences. To produce cisgenic plants any suitable technique used for production of transgenic organisms may be used. Genes must be isolated, cloned or synthesized and transferred back into a recipient where stably integrated and expressed. Sometimes the term cisgenesis is also used to describe an Agrobacterium-mediated transfer of a gene from a crossable, sexually compatible, plant where T-DNA borders may remain in the resulting organism after transformation. This is referred further as cisgenesis with T-DNA borders. Intragenesis is a genetic modification of a recipient organism that leads to a combination of different gene fragments from donor organism(s) of the same or a sexually compatible species as the

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<sup>67</sup> EFSA Panel on Genetically Modified Organisms (GMO) and Panel on Biological Hazards (BIOHAZ); Scientific Opinion on Statement on a request from the European Commission for the assessment of the scientific elements supporting the prohibition for the placing on the market of GM potato EH92-527-1 for cultivation purposes in Austria. EFSA Journal 2012;10(3):2627. [13 pp.] doi:10.2903/j.efsa.2012.2627. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2627.htm> (accessed 04.07.12)

<sup>68</sup> EFSA Panels on GMO and AHAW; 2012. Scientific Opinion on the Guidance on the risk assessment of food and feed from genetically modified animals and animal health and welfare aspects. EFSA Journal 2012;10(1):2501. [43 pp.] doi:10.2903/j.efsa.2012.2501. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2501.htm> (accessed 10.07.12)

recipient. These may be arranged in a sense or antisense orientation compared to their orientation in the donor organism. Intragenesis involves the insertion of a reorganised, full or partial coding region of a gene frequently combined with another promoter and/or terminator from a gene of the same species or a crossable species.” EFSA concluded that similar hazards can be associated with cisgenic and conventionally bred plants, while novel hazards can be associated with intragenic and transgenic plants.<sup>69</sup>

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<sup>69</sup> EFSA Panel on Genetically Modified Organisms (GMO); Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 2012;10(2):2561. [33 pp.] doi:10.2903/j.efsa.2012.2561. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2561.htm> (accessed 10.07.123)

## Health and Nutrition

See nutrition declaration requirements of the new Food Information regulation above and the Transfer of Functions (Food) Regulations 2011 below.

### Nutrition and Health Claims

General information on nutrition and health claims:

[EFSA](#) and the [Commission](#) have websites dedicated to nutrition and health claims, the latter including a database of permitted nutrition claims and their conditions of use, authorised health claims, their conditions of use and applicable restrictions, if any; non-authorised health claims and the reasons for their non-authorisation and EU legal measures for specific health claims.

Regulation (EC) No 1924/2006 harmonises the provisions that relate to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. Health claims are only authorised for use in the Community after a scientific assessment of the highest possible standard has been carried out by EFSA. EFSA in March 2012 published guidance from its Panel on Dietetic Products, Nutrition and Allergies (NDA) on scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations. This guidance was drawn from scientific opinions of the NDA Panel on such health claims and is based on the experience gained to date with the evaluation of health claims in these areas. It was not intended as an exhaustive list of beneficial effects and studies/outcome measures which are acceptable but rather presents examples drawn from evaluations already carried out in order to illustrate the approach of the Panel, as well as some examples which are currently under consideration within ongoing evaluations. A draft of this guidance document, endorsed by the NDA Panel on 25 March 2011, was released for public consultation from 26 April 2011 to 31 August 2011.

### Dietary Reference Values

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) in February published a scientific opinion on dietary reference values for protein. Several health outcomes possibly associated with protein intake were considered but data were found to be insufficient to establish DRVs. For healthy adults of both sexes, the average requirement (AR) is 0.66 g protein/kg body weight per day based on nitrogen balance data. Other reference data are given.<sup>70</sup>

An externally sourced literature review to provide EFSA with an up-to-date review of health outcomes upon which Dietary Reference Values could potentially be based for vitamins A, C, E, and K was published in March 2012. Comprehensive literature searches were carried out using the OVID system with access to most important databases including: Medline, All EBM Reviews and Medline In-Process & Other Non-Indexed Citations.<sup>71</sup>

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<sup>70</sup> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on Dietary Reference Values for protein. EFSA Journal 2012;10(2):2557 [66 pp.]. doi:10.2903/j.efsa.2012.2557. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2557.htm> (accessed 10.07.12)

<sup>71</sup> Literature search and review related to specific preparatory work in the establishment of Dietary Reference Values <http://www.efsa.europa.eu/en/supporting/pub/256e.htm> (Accessed 04.07.12)

## Goat milk protein

In March 2012 EFSA published a scientific opinion on the suitability of goat milk protein as a source of protein in infant and follow-on formulae. The NDA Panel concluded that protein from goat milk can be suitable as a protein source for infant and follow-on formulae, provided the final product complies with the compositional criteria laid down in Directive 2006/141/EC.<sup>72</sup>

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<sup>72</sup> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the suitability of goat milk protein as a source of protein in infant formulae and in follow-on formulae. EFSA Journal 2012;10(3):2603. [18 pp.]. doi:10.2903/j.efsa.2012.2603. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2603.htm> (Accessed 04.07.12)

# Regulation

## Imports of Organic Products

Commission Implementing Regulation (EU) No 126/2012 of 14 February 2012 amending Regulation (EC) No 889/2008 as regards documentary evidence and amending Regulation (EC) No 1235/2008 as regards the arrangements for imports of organic products from the United States of America.<sup>73</sup>

The Commission, following a request from US authorities, has concluded that US rules governing the production and controls of organic agricultural products are equivalent to those laid down in Regulation (EC) No 834/2007. Consequently, the US is included in the list set out in Annex III to Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries. Regulation (EC) No 889/2008 also refers.

## Official controls - products of non- animal origin

Commission Regulation (EC) No 669/2009 ( 2 ) lays down rules concerning increased levels of official controls to be carried out on imports of feed and food of non- animal origin listed in Annex I thereto (the list). The list is regularly reviewed in light of changing circumstances. Further changes were made in December 2011. The chemical analytes cover pesticides, mycotoxins and metals and hence there are no novel analytical implications for the GC.<sup>74</sup>

## EFSA

### EFSA Science Strategy 2012-2016 & other Corporate Documents

The Science Strategy 2012-2016 lays out the vision of how EFSA will continue to support the European food safety system over the next five years and meet the demands that are placed upon it and was put out for consultation in 2011. EFSA received 62 comments from 16 organisations and individuals, many supportive but some critical.<sup>75</sup> In the coming five years, EFSA's scientific activities will focus on four key strategic objectives:

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<sup>73</sup> Commission Implementing Regulation (EU) No 126/2012 of 14 February 2012 amending Regulation (EC) No 889/2008 as regards documentary evidence and amending Regulation (EC) No 1235/2008 as regards the arrangements for imports of organic products from the United States of America <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:041:0005:0011:EN:PDF> (accessed 05.06.12)

<sup>74</sup> Commission Implementing Regulation (EU) No 1277/2011 of 8 December 2011 amending Annex I to 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:2011:327:0042:0048:EN:PDF> accessed 23.01.12.

<sup>75</sup> European Food Safety Authority; Outcome of the public consultation on the Draft Science Strategy 2012-2016. Supporting Publications 2012:EN-224. [42 pp.]. Available at <http://www.efsa.europa.eu/en/supporting/pub/224e.htm> (accessed 10.07.12)

- further develop the excellence of EFSA's scientific advice and its openness, transparency, independence and responsiveness;
- optimise the use of risk assessment capacity in the EU;
- develop and harmonise methodologies and approaches to assess risks associated with the food chain;
- strengthen the scientific basis for risk assessment and risk monitoring.<sup>76</sup>

EFSA moved into new, purpose-built premises in Parma in January 2012 and published<sup>77</sup> its 2012 work plan, including an organisation diagram, in March 2012. Key work areas include meat inspection building on the momentum to modernise traditional meat inspection, transmissible spongiform encephalopathies (TSEs), zoonoses, dietary reference values, pesticides including the "cocktail effect", food and feed additives, novel foods, food contact materials, genetically modified organisms and micro-organisms, animal welfare indicators endocrine active substances and environmental risk assessment.

The work plan stems from EFSA's Science Strategy 2012-2016. Membership of eight of EFSA's Scientific Panels and its Scientific Committee will be re-established over the coming year and the Management Board will be partially renewed. The results of the ongoing external evaluation of EFSA are due in June 2012. EFSA aims to continue to strengthen its cooperation with national food safety agencies and scientific organisations in the Member States in order to pool risk assessment resources recognising difficult economic climate but will allocate grants and contracts worth €9.2 million to Member State organisations, an increase of €1 million over 2011.

The Stakeholder Consultative Platform will continue to be strengthened and will be renewed when its current mandate expires in mid-2012. EFSA will implement in 2012 a pilot project allowing observers to attend a number of Scientific Panel meetings. A preliminary rolling multi-annual plan for 2013-2015 will outline the main challenges and deliverables and integrate critical support activities (information technology, human capital development and knowledge management).

EFSA will continue to develop its ability to identify and deal with emerging risks, in line with the 2010 *Emerging Risks Report* and the Science Strategy. A set of risk communication guidelines, developed in collaboration with Member States, will be published.

Other EFSA corporate documents published in January 2012 were the [Annual Management Plan 2012](#) and the [Budget and Establishment Plan 2012](#).

## **Toxicology**

### **Benchmark Dose and Margin of Exposure**

Assessing the risk of low concentrations in food or feed of substances that are both genotoxic and carcinogenic is not easy as historically and in theory there was assumed to be no concentration of intake below which there is zero risk. However EFSA has recommended the margin of exposure (MOE) approach. The MOE approach uses a reference point, often taken from an animal study and corresponding to a dose that causes a low but measurable response in animals. This reference point is then compared with various dietary intake estimates in humans, taking into account differences in consumption patterns. The MoE is calculated from the benchmark dose (BMD), a standardised reference point derived from

<sup>76</sup> EFSA Science Strategy 2012 – 2016, available at <http://www.efsa.europa.eu/en/corporate/pub/sciencestrategy12.htm> (accessed 10.07.12)

<sup>77</sup> EFSA Work Plan 2012 available at <http://www.efsa.europa.eu/en/corporate/pub/workplan12.htm> (Accessed 10.07.12)

animal data by mathematical modelling. EFSA recommends the use of the BMDL10 - benchmark dose lower confidence limit 10% - which is an estimate of the lowest dose which is 95% certain to cause no more than a 10% cancer incidence in rodents. The benchmark dose approach can also be applied to human data when available. The MoE is calculated by dividing the BMDL10 by the exposure dose. In cases where the data would be unsuitable for deriving a benchmark dose, use of the T25, representing the dose corresponding to a 25% incidence of tumours, is recommended.<sup>78</sup> An example of the use of such approaches applied to furan is that of Carthew *et al.*<sup>79</sup> while general discussions have been published<sup>80,81</sup>. The EFSA Scientific Committee reiterated its view expressed in 2005 that in general a margin of exposure of 10,000 or higher, if it is based on the BMDL10 from an animal study, and taking into account overall uncertainties in the interpretation, would be of low concern from a public health point of view; the magnitude of an MOE however only indicates a level of concern and does not quantify risk. The Scientific Committee also reiterated dialogue is recommended on the weighing of the potential health significance of the magnitude of particular MOEs and how to band MOEs with respect to conclusions that use expressions such as 'high concern', 'low concern', or 'unlikely to be of safety concern'. EFSA has issued a statement that the MoE approach can be used, with caveats, in the evaluation of impurities that are both genotoxic and carcinogenic found in food or feed additives when the additives are being assessed. See above 'Food Additives' section<sup>82</sup>.

## Combined actions of chemicals in food

In January 2012 an external report was published by EFSA on the state of the science on combined actions of chemicals in food through dissimilar modes of action and proposals for a science-based approach for performing related cumulative risk assessment. For many years it has been recognised that risk assessments of single substances leaves consumers unprotected from effects that combine and arise from similar or indeed dissimilar compounds.

The report details the steps taken to assess the literature and summarise the state of the science on combined actions of chemicals in food. It proposes a science based approach for a cumulative risk assessment, CRA, that unifies the assessment of similarly and dissimilarly acting chemicals based on pragmatic use of assessment approaches derived from the concept of dose addition, DA. The report confirms that there is no current example of a situation in which the concept of independent action (IA) provides an accurate prediction that is also more conservative than DA, supporting the use of DA as a conservative default in CRA. The approach incorporates a tiered framework and abandons distinctions according to (presumed) modes of action of chemicals at lower tiers of the analysis and to assess all the chemicals that occur together in the exposure scenario under investigation. At higher tiers, and only if the risks identified at lower tiers are deemed unacceptable, should chemicals be grouped together according to their ability to evoke a common adverse outcome. Features of the proposed approach are illustrated in three case studies. The overall conclusion of this project is that it is feasible and justified to utilise CRA methods and tiered framework analyses

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<sup>78</sup> Opinion of the Scientific Committee on a request from EFSA related to A Harmonised Approach for Risk Assessment of Substances Which are both Genotoxic and Carcinogenic, (Request No EFSA-Q-2004-020). (Adopted 18 October 2005), *The EFSA Journal* (2005) 282, 1-31, available at <http://www.efsa.europa.eu/en/efsajournal/doc/282.pdf> (accessed 03 07 12)

<sup>79</sup> Philip Carthew, Michael DiNovi, R. Woodrow Setzer, 2010, Application of the margin of exposure (MoE) approach to substances in food that are genotoxic and carcinogenic Example: Furan (CAS No. 110-00-9), *Food and Chemical Toxicology* 48, S69-S74

<sup>80</sup> O'Brien *et al.*, 2006, Approaches to the risk assessment of genotoxic carcinogens in food: A critical appraisal, *Food and Chemical Toxicology* 44, 1613 - 1635

<sup>81</sup> Barlow *et al.*, 2006, Risk assessment of substances that are both genotoxic and carcinogenic, *Food and Chemical Toxicology* 44, 1636 - 1650

<sup>82</sup> EFSA Scientific Committee; Scientific Opinion on the applicability of the Margin of Exposure approach for the safety assessment of impurities which are both genotoxic and carcinogenic in substances added to food/feed. *EFSA Journal* 2012;10(3):2578. [5 pp.] doi:10.2903/j.efsa.2012.2578. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2578.htm> (accessed 03 07 12)

originally developed for similarly acting mixtures also for combinations of dissimilarly acting chemicals.<sup>83</sup>

## Default values

To enhance harmonisation of risk assessment default values for body weight, liquid intake, dose conversion, uncertainty factors and guidance on rounding of figures such as health-based guidance values were given in advice published by EFSA in March 2012. For example a body weight of 70 kg should be used as default for the European adult population (aged above 18 years). The advice notes that the degree of precision for measured values is determined by the precision of the analytical methodology, emphasising the need for careful evaluation of measurement uncertainty.<sup>84</sup>

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<sup>83</sup> Kortenkamp A, Evans R, Faust M, Kalberlah F, Scholze M and Schuhmacher-Wolz U. Investigation of the state of the science on combined actions of chemicals in food through dissimilar modes of action and proposal for science-based approach for performing related cumulative risk assessment. Supporting Publications 2012:EN-232. [233pp.]. Available at <http://www.efsa.europa.eu/en/supporting/pub/232e.htm> (accessed 10.07.12)

<sup>84</sup> EFSA Scientific Committee; Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. EFSA Journal 2012;10(3):2579. [32 pp.] doi:10.2903/j.efsa.2012.2579. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/2579.htm> See also [Guidance on default values: outcome of the public consultation](#) (Accessed 04.07.12)



## Feeding Stuffs and Fertilisers

### Ergot

The Commission has recommended<sup>85</sup> that Member States should, with the active involvement of feed and food business operators, monitor the presence of ergot alkaloids in cereals and cereal products intended for human consumption or intended for animal feeding, in pasture/forage grasses for animal feeding and in compound feed and food. For further details see 'Ergot' in the Food Safety, Contaminants section above.

### Dioxins and PCBs

Commission Regulation (EU) No 277/2012 of 28 March 2012 amended Annexes I and II to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum permitted concentrations and action thresholds for dioxins and polychlorinated biphenyls in feed.<sup>86</sup>

Commission Regulation (EU) No 278/2012 of 28 March 2012<sup>87</sup> amended Regulation (EC) No 152/2009 as regards the determination of the levels of dioxins and polychlorinated biphenyls in animal feed to mirror provisions established for food (see above). Usefully, aggregate samples obtained according to the Regulation are considered representative for the lots or sub-lots from which they are taken and compliance with maxima in Directive 2002/32/EC are established on the basis of the concentrations determined in the laboratory samples.

### Feed Additives

Alpha-galactosidase (EC 3.2.1.22), dicopper chloride trihydroxide, lactococcus lactis (NCIMB 30117), lactobacillus pentosus (DSM 14025), lactobacillus plantarum (DSM 8862 and DSM 8866), 6-phytase (EC 3.1.3.26), a preparation of caraway oil, lemon oil with certain dried herbs and spices, sodium bisulphate and monensin sodium were authorised as feed additives.

Commission Regulation (EU) No 223/2012 of 14 March 2012 amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I and IV thereto to technical progress was made<sup>88</sup> Article 3 of Regulation (EC) No 2003/2003 provides that a fertiliser belonging to a type of fertiliser listed in Annex I thereto and complying with prescribed conditions may be designated EC fertiliser. These include some that may be sold only in the form of fine powders, while others may be

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<sup>85</sup> Commission Recommendation of 15 March 2012 on the monitoring of the presence of ergot alkaloids in feed and food <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:077:0020:0021:EN:PDF>

<sup>86</sup> Commission Regulation (EU) No 277/2012 of 28 March 2012 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:091:0001:0007:EN:PDF> (accessed 21.06.12)

<sup>87</sup> Commission Regulation (EU) No 278/2012 of 28 March 2012 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:091:0008:0022:EN:PDF> (accessed 21.06.12)

<sup>88</sup> Commission Regulation (EU) No 223/2012 of 14 March 2012 amending Regulation (EC) No 2003/2003 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:075:0012:0023:EN:PDF> (accessed 19.06.12)

sold in the form of suspensions. Fertilisers in the form of suspensions pose less risk to the health of farmers than fine powders which could be inhaled as dusts and the Regulation extends the option of using suspensions to include manganese micronutrient fertiliser types and the range of ingredients permitted in existing boron and copper fertiliser suspensions are also be extended.

Regulation (EC) No 2003/2003 envisages the use of complexing agents as ingredients in micro-nutrient fertilisers. However, no such fertilisers have been designated EC fertiliser because no list of authorised complexing agents has yet been established in Annex I. Suitable complexing agents (lignosulfonic acid salts) are now available and are added to the list of authorised complexing agents and corresponding type designations created. Existing type designations for fertiliser solutions are also adapted to allow the use of complexing agents, but each such solution should not contain more than one complexing agent to facilitate official controls. Regulation (EC) No 2003/2003 provides a set of rules for the labelling of mixed micro-nutrient fertilisers but does not provide for the corresponding type designations in its Annex I. Regulation (EU) No 137/2011 introduced Table E.2.4 in Section E.2 of Annex I to Regulation (EC) No 2003/2003 containing the corresponding type designations and clearer rules for mixtures of micro-nutrient fertilisers. However, Table E.2.4 requires some labelling information, which in certain cases would not be in conformity with that required by Articles 6(6) and 23(2) of Regulation (EC) No 2003/2003. Table E.2.4 is therefore be amended accordingly with a transitional period.

Organic chelating agent N,N'-di(2-hydroxybenzyl)ethylenediamine-N,N'-diacetic acid (HBED), nitrification inhibitors dicyandiamide/1,2,4 triazole (DCD/TZ) and 1,2,4 triazole/3-methylpyrazole (TZ/MP), urease inhibitor N-(2-nitrophenyl)phosphoric triamide (2-NPT) are authorised.

Regulation (EC) No 2003/2003 requires the control of EC fertilisers in accordance with the methods of sampling and analysis that are described in Annex IV thereto. However, some of those methods are not internationally recognised and are replaced by EN standards recently developed by the European Committee for Standardisation. EN standards are usually validated by means of an inter-laboratory comparison to quantify the reproducibility and repeatability of the analytical methods. A distinction between validated EN Standards and non-validated methods is be made to identify those EN Standards which have proven statistical reliability. Lastly the full text of the analytical methods in Annex IV to Regulation (EC) No 2003/2003 is replaced by references to the EN standards published by the European Committee for Standardisation.

## **Guidance on production of dossiers for feed additives**

The EFSA Panel on Additives and Products or Substances used in Animal Feed in January 2012 produced a series of guides for those wishing to produce dossiers for feed additives.

[Guidance on additives already authorised in food](#)

[Guidance on user safety](#)

[Guidance on consumer safety](#)

[Guidance on zootechnical additives](#)

[Guidance on nutritional additives](#)

[Guidance on sensory additives](#)

[Guidance on technological additives](#)