Food and feed law:

A review of changes in food and feed legislation and associated activity affecting the UK

October – December 2015

Government Chemist Programme Report

Department
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Introduction to 'Food and feed law' review series

This is the fifth in a series of quarterly reports that will provide regular updates on developments in food and feed law and related scientific and regulatory issues.

They form part of the Government Chemist project 'Support for the Government Chemist statutory function', which is one of the projects in the 2014-2017 programme. The primary purpose of the report is to track changes in food and agricultural legislation, concentrating on legislative changes that relate to chemical measurement and the role of the Government Chemist. It also includes general issues in food and feed to ensure contextual awareness.

The reports in this series will group the legislation into six broad categories; although the categories may not always be populated in every report.
The categories are:

1. **Cross-cutting issues**
2. **Food safety**
    - Including contaminants, food contact materials, and additives.
3. **Consumer choice and prevention of fraud**
    - Including composition and general labelling.
4. **Health and nutrition**
    - Including nutrition labelling, nutrients and supplements.
5. **Regulation**
    - Regulatory activities and overarching provisions.
6. **Feeding stuffs and fertilisers**
    - 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.

Please note – legislation in force and made prior to October 2015 will not necessarily be reiterated herein. 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.

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

The sources of information used have been Office of Public Sector Information (OPSI), Food Standards Agency (FSA) updates, European Food Safety Authority (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.

Executive summary

This report provides an update on developments in food and feed law and related scientific and regulatory issues for the period from October to December 2015.

Following on from the UK cumin case referred by the Food Standards Agency (FSA) to the Government Chemist for investigation and reported in our previous April – June report, the Government Chemist was asked to investigate a sample of paprika alleged to contain almond. Work on this case concluded during the quarter and although limitations still remain in the state of the science, the referred sample was found to contain Prunus protein(s) and DNA the origin of which is consistent with almond rather than mahaleb.

Arguably the most significant legislative change in the quarter was the modernisation of European law on novel food, food absent for use for human consumption to a significant degree within the EU before 15 May 1997, including in the Member States irrespective of the dates of their accession. The scope of the Regulation remains similar to the previous law but coverage now includes engineered nanomaterials, cloned animals, whole insects and their parts, food with a new or intentionally modified molecular structure, food from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae, and food from material of mineral origin. There is also a category covering food from plants obtained by non-traditional propagating practices. The definition of novel food also covers food consisting of certain micelles or liposomes. The new Regulation simplifies the current authorisation procedures, and sets out criteria for the assessment of the safety risks arising from novel foods by the European Food Safety Authority.

Control of contaminants is frequently updated and almost always features in our quarterly updates. There were developments on ergot, and administrative clarifications on dioxins testing in feed. Ergot (from the fungus *Claviceps purpurea*) in cereals presents a high toxicity risk for animals and humans due to the alkaloid content and continued to receive attention with maximum levels of ergot sclerotia in certain unprocessed cereals and the provisions on monitoring and reporting. Interestingly it appears competent authorities may take appropriate measures, in accordance with Regulation 178/2002 to impose restrictions on the placing of food on the market or to require withdrawal of such food from the market, where the food is found unsafe because of the level of ergot alkaloids, despite its compliance with the maximum level on ergot sclerotia.

A coordinated multiannual pesticides control programme of the EU for 2016 - 2018 was published and changes to maximum residue levels (MRLs) were noted some pesticides and veterinary medicinal products. Minor changes were made in respect of food additives and flavourings are recorded.

The standards for and analysis of various grades of olive oil were updated in the quarter. A major report on acrylamide, a new database of more than 240 000 DNA sequences appearing in genetically modified organisms, a Public Health England report on sugar and a new Food law prosecutions database are also worthy of note.

No major analytical difficulties were identified during this review of developments in the quarter however there remain problems in the confirmation of the presence of certain allergens in food.

Contents

1 Cross-cutting issues

1.1 Paprika alleged to contain almond

Following on from the UK cumin case referred by the Food Standards Agency (FSA) to the Government Chemist for investigation and reported in our previous April – June report, the Government Chemist was asked to investigate a sample of paprika alleged to contain almond. Work on this case concluded during the quarter and although limitations still remain in the state of the science, the referred sample was found to contain Prunus protein(s) and DNA the origin of which is consistent with almond rather than mahaleb.[1]

1.2 Uncertainty in food risk assessment

We are grateful to Graham Reed for drawing attention to an EFSA consultation[2] (closed September 2015) on Guidance on how to characterise, document and explain all types of uncertainty arising in EFSA's scientific assessments. Uncertainty was defined as referring to all types of limitations in the knowledge available to assessors at the time an assessment is conducted and within the time and resources available for the assessment. The Guidance is applicable to all areas of EFSA and all types of scientific assessment, including risk assessment and all its constituent parts (hazard identification and characterisation, exposure assessment and risk characterisation). 'Assessor' is used as a general term for those providing scientific advice, including risk assessment, and 'decision-maker' for the recipients of the scientific advice, including risk managers. The Guidance does not prescribe specific methods for uncertainty analysis but rather provides a harmonised and flexible framework within which different methods may be selected, according to the needs of each assessment.[3]

1.3 Emerging Risks

The annual report for 2014 of the Emerging Risks Exchange Network, EREN, was published[4] and although this was dealt with in our report on Quarter July – September[5] it is probably worth retaining the list of emerging concerns:

1 Okadaic acid in Manila clams in Italy
2 Heat-generated food contaminants
3 Pomegranate substitution
4 Adulteration of lamb dishes with other meat species
5 Novel phleboviruses
6 Detection of *Aethina tumida* in Southern Italy
7 Clenbuterol as emerging risk in the food chain
8 Long term effects of food emulsifiers on intestinal barriers
9 Other active substances than vitamins and mineral used in food supplements
10 Potential issues with the transition from long-chain poly- and perfluorinated alkyl substances (PFASs) to new fluorinated alternatives.

[1] https://www.gov.uk/government/news/paprika-referee-sample-further-testing-identifies-almond-present
[2] http://www.efsa.europa.eu/en/consultations/call/150618
[3] http://www.efsa.europa.eu/sites/default/files/consultation/150618.pdf
[4] http://www.efsa.europa.eu/en/supporting/pub/839e
[5] https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2015

2 Food safety

2.1 Contaminants

Regulation (EC) No 1881/2006 remains the primary European legislation, the latest consolidated version of which was published in November 2015[6]. This is a measure that is frequently updated and almost always features in our quarterly updates.

2.1.1 Inorganic arsenic, iAs

Arsenic was discussed extensively in our previous quarterly update[7] with Commission Regulation 2015/1006[8] having amended Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in certain foodstuffs. During the quarter July – September 2015 Commission Recommendation 2015/1381[9] recommended the monitoring of inorganic arsenic in food by Member States during the years 2016, 2017 and 2018.

2.1.2 Polycyclic aromatic hydrocarbons

Commission Regulation 2015/1903[10] amended Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in cocoa fibre, banana chips, food supplements, dried herbs and dried spices. This adds further foodstuffs to the lists for which PAHs are given limits including herbs, spices and banana chips.

2.1.3 Mycotoxins

2.1.3.1 Ergot

The occurrence of ergot bodies (sclerotia of the fungus *Claviceps purpurea*) in cereals presents a high toxicity risk for animals and humans due to the alkaloid content.[11],[12] The presence of ergot alkaloids in cereal grains is approximately related to the presence of ergot sclerotia in cereal grains but ergot alkaloids can also be present in the dust from ergot sclerotia adsorbed to the cereal grains. It is therefore important to set maximum levels for ergot sclerotia as a first step while gathering further data on the presence of ergot alkaloids in cereals and cereal products. However it is acknowledged that compliance with the maximum level for ergot sclerotia does not necessarily guarantee the safety of food as regards the presence of ergot alkaloids. Commission Regulation 2015/1940[13] amended Regulation (EC) No 1881/2006 as regards maximum levels of ergot sclerotia in certain unprocessed cereals and the provisions on monitoring and reporting. A limit for unprocessed cereals (with the exception of corn and rice) of 0.5 g kg^{-1} (grams of ergot sclerotia per kilogram of product) has been established. Competent authorities may take appropriate measures, in accordance with Article 14(8) of Regulation (EC) No 178/2002 of the European Parliament and of the Council to impose restrictions on the placing of food on the market or to require withdrawal of such food from the market, where the food is found unsafe

[6] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1453831421062&uri=CELEX:02006R1881-20151118
[7] https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2015
[8] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.161.01.0014.01.ENG
[9] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.213.01.0009.01.ENG
[10] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.282.01.0011.01.ENG
[11] Vermeulen, Ph, et al. "Online detection and quantification of ergot bodies in cereals using near infrared hyperspectral imaging." *Food Additives & Contaminants: Part A* 29.2 (2012): 232-240.
[12] Walker, M. European & UK Regulation of Food & Feed, October 2011 – March 2012, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/329106/EU_and_UK_regulation_of_food_and_feed_review.pdf
[13] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.283.01.0003.01.ENG

because of the level of ergot alkaloids, despite its compliance with the maximum level on ergot sclerotia.

2.1.4 Erucic acid

Regulation 2015/2284 of the European Parliament and of the Council[14] repealed Council Directive 76/621/EEC relating to the fixing of the maximum level of erucic acid in oils and fats.

2.2 Non regulated contaminants

There are some contaminants for which legislation is not currently appropriate. Some compounds arise as artefacts of food processing or even cooking, for example acrylamide.

2.2.1 Acrylamide

In November 2015 FSA published[15] the second in a regular series of science updates from Chief Scientific Advisor Professor Guy Poppy. This issue focuses on chemical risks in food. The major topic discussed in the report is acrylamide, the chemical contaminant that forms in certain foods during cooking. Regulators have been working with the food industry to reduce levels of acrylamide in processed foods and have long-standing advice to consumers on how to minimise the risks when cooking at home. The report looks at how the chemical was first identified, what the risks are to consumers, and how FSA and industry are reacting to this risk.[16]

2.3 Food additives

Annex II to Regulation (EC) No 1333/2008 lays down a European Union list of food additives approved for use in foods and their conditions of use, and Annex I to Regulation (EC) No 1334/2008 lays down a European Union list of flavourings and source materials approved for use in and on foods and their conditions of use. Commission non-official guidance describes the food categories in Part E of Annex II to Regulation 1333/2008.[17]

In the quarter, Commission Implementing Regulation 2015/1739[18] amended Annex II to Regulation 1333/2008 and the Annex to Regulation 231/2012 as regards the use of the iron tartrate as an anti-caking agent in salt and its substitute, providing specifications for this including purity, impurity levels and assay.

Commission Implementing Regulation 2015/1832[19] amended Annex II to Regulation 1333/2008 as regards the use of Erythritol (E 968) as a flavour enhancer in energy-reduced or with no added sugars flavoured drinks at a maximum level of 1.6 %. Erythritol helps mitigate any off-tastes and lingering sweetness associated with the use of high-intensity sweeteners

Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.

[14] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.327.01.0023.01.ENG&toc=OJ:L:2015:327:TOC
[15] https://www.food.gov.uk/news-updates/news/2015/14655/chief-scientific-advisor-s-report-acrylamide
[16] https://www.food.gov.uk/sites/default/files/csa-acrylamide-report.PDF
[17] http://ec.europa.eu/food/food/fAEF/additives/guidance_en.print.htm
[18] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.253.01.0003.01.ENG
[19] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.266.01.0027.01.ENG

2.3.1 Flavourings

Flavourings and certain food ingredients with flavouring properties are controlled by Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008[20]. In the quarter, Commission Implementing Regulation 2015/1760[21] amended Annex I to Regulation 1334/2008 to remove from the Union list of the flavouring substance p-mentha-1,8-dien-7-al.

2.4 Food contact materials

Commission Regulation 2015/1906[22] amended Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods. The amendment clarifies regulatory procedures consequent upon Decision 1999/468/EC having been replaced by Regulation (EU) No 182/2011.

2.5 Marine biotoxins

No new centrally published updates in this quarter.

2.6 Pesticides

Commission Implementing Regulation 2015/595[23] sets out a coordinated multiannual control programme of the EU for 2016, 2017 and 2018 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

Regulation (EC) No 396/2005 governs maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin; Annexes II, III and V to the regulation were amended as follows in the quarter:

Commission Regulation 2015/1040[24] amended the Annexes as regards MRLs for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products. This is a comprehensive Regulation applying to a wide range of food types.

Commission Implementing Regulation 2015/1101[25] amended the Annexes as regards MRLs for difenoconazole, fluopicolide, fluopyram, isopyrazam and pendimethalin in or on certain products.
Commisssion Regulation 2015/1200[26] amended the Annexes as regards MRLs for amidosulfuron, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin in or on certain products.

Commission Implementing Regulation 2015/1608[27] amended Annex IV to Regulation (EC) No 396/2005 as regards MRLs for capric acid, paraffin oil (CAS 64742-46-7), paraffin oil (CAS 72623-86-0), paraffin oil (CAS 8042-47-5), paraffin oil (CAS 97862-82-3), lime sulphur and urea in or on certain products.

[20] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1445980490072&uri=CELEX:02008R1334-20150729
[21] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.257.01.0027.01.ENG
[22] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.278.01.0011.01.ENG
[23] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.099.01.0007.01.ENG
[24] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.167.01.0010.01.ENG
[25] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.181.01.0027.01.ENG
[26] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.195.01.0001.01.ENG
[27] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.249.01.0014.01.ENG

Commission Regulation 2015/552[28] amended Annexes II, III and V to Regulation (EC) No 396/2005 as regards maximum residue levels for 1,3-dichloropropene, bifenox, dimethenamid-P, prohexadione, tolylfluanid and trifluralin in or on certain products. This list of products is very extensive and goes acrosss all types of foodtsuffs.

Commission Implementing Regulation 2015/603[29] amended Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-naphthyloxyacetic acid, acetochlor, chloropicrin, diflufenican, flurprimidol, flutolanil and spinosad in or on certain products.

Commission Regulation 2015/896[30] amends Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for *Trichoderma polysporum* strain IMI 206039, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strains IMI 206040 and T11, *Trichoderma harzianum* strains T-22 and ITEM 908, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma asperellum* (strain T34), *Trichoderma atroviride* strain I-1237, geraniol, thymol, sucrose, ferric sulphate (iron (III) sulphate), ferrous sulphate (iron (II) sulphate) and folic acid in or on certain products.

Commission Regulation 2015/1040[31] amends Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products. This is a comprehensive Regulation applying to a wide range of food types.

Commission Implementing Regulation 2015/1101[32] which Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for difenoconazole, fluopicolide, fluopyram, isopyrazam and pendimethalin in or on certain products.

Commisssion Regulation 2015/1200[33] amends 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, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin in or on certain products.

Commission Regulation 2015/1910[34] amends Annexes III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for guazatine in or on certain products. The limit is now 0.05 mg/kg for the sum of guazatine and guazatine acetate, which is the lowest level which can be determined analytically.

Commission Implementing Regulation 2015/2075 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 abamectin, desmedipham, dichlorprop-P, haloxyfop-P, oryzalin and phenmedipham in or on certain products. This covers the MRLs for these pesticides across a wide range of fruits, vegetables, nuts, herbs, spices and meats.

[28] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.092.01.0020.01.ENG
[29] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.100.01.0010.01.ENG
[30] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.147.01.0003.01.ENG
[31] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.167.01.0010.01.ENG
[32] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.181.01.0027.01.ENG
[33] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.195.01.0001.01.ENG
[34] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.280.01.0002.01.ENG

Commission Implementing Regulation 2015/2084 approved the active substance flupyradifurone, in accordance with Regulation (EC) No 1107/2009 and amended the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/2085 approved the active substance mandestrobin, in accordance with Regulation (EC) No 1107/2009 and amended the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/2105 approved the active substance flumetralin (N-(2-chloro-6-fluorobenzyl)-N-ethyl-α,α,α-trifluoro-2,6-dinitro-p-toluidin), as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 and amended Commission Implementing Regulation (EU) No 540/2011, providing it has a purity of mot less than 98 % and the impurity Nitrosamine (calculated as nitroso-dimethylamine) does not exceed 0.01 % in the technical material.

Commission Implementing Regulation 2015/2198 approved the active substance rescalure ((3S,6R)-(3S,6S)-6-isopropenyl-3-methyldec-9-en-1-yl acetate), at a purity of not less than 75 %, and with a ratio of (3S,6R)/(3S,6S) shall be in a range of 55/45 to 45/55, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/2233 amended Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance haloxyfop-P.

Regulation (EC) No 1107/2009 deals with the placing of plant protection products on the market. The following amendments were made during the quarter:

Commission Implementing Regulation 2015/1885[35] amended Implementing Regulation (EU) No 540/2011 to extend the approval periods of the active substances 2,4-D, acibenzolar-s-methyl, amitrole, bentazone, cyhalofop butyl, diquat, esfenvalerate, famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), glyphosate, iprovalicarb, isoproturon, lambda-cyhalothrin, metalaxyl-M, metsulfuron methyl, picolinafen, prosulfuron, pymetrozine, pyraflufen-ethyl, thiabendazole, thifensulfuron-methyl and triasulfuron. The approval for these substances is extended to 30 June 2016 since the assessment of the substances has been delayed for reasons beyond the control of the applicants.

Commission Implementing Regulation 2015/2033 renewed the approval of the active substance 2,4-D in accordance with Regulation (EC) No 1107/2009 and amended the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/2046[36] concerns the non-approval of *Artemisia absinthium* L. as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. The documentation provided by the applicant showed that *Artemisia absinthium* L. fulfils the criteria of a foodstuff as defined in Article 2 of Regulation (EC) No 178/2002. However, alcoholic beverages from Artemisia species are included in Part B of Annex III to Regulation (EC) No 1334/2008 which sets maximum levels of certain substances in flavourings. The Artemisia species cannot be used as a foodstuff without qualification. Specific concerns were identified by

[35] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.276.01.0048.01.ENG
[36] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.300.01.0006.01.ENG

EFSA regarding exposure to thujone, absinthin and ferulic acid and, as a result, the assessment of the risk to operators, workers, bystanders, consumers and non-target organisms could not be finalized and the concerns could not be eliminated. Consequently it was appropriate not to approve *Artemisia absinthium* L. as basic substance. This Regulation does not prejudice the submission of a further application for the approval of *Artemisia absinthium* L. as basic substance in accordance with Article 23(3) of Regulation (EC) No 1107/2009.

Similar considerations (exposure to arctigenin, chlorogenic and caffeic acids) applied in Commission Implementing Regulation 2015/2082[37] that concerns the non-approval of *Arctium lappa* L. (aerial parts) as a basic substance in accordance with Regulation (EC) No 1107/2009.
Exposure to camphor, thujones and 1,8-cineole influenced Commission Implementing Regulation 2015/2083[38] in the non-approval of *Tanacetum vulgare* L. as a basic substance in accordance with Regulation (EC) No 1107/2009.

Commission Implementing Regulation 2015/2047 renewed the approval of the active substance esfenvalerate, the substance must have a purity greater than or equal to 83% and contain no more than 1% of toluene as an impurity.

2.7 Transmissible spongiform encephalopathies

Regulation (EC) No 999/2001 laid down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals. It applies to the production and placing on the market of live animals and products of animal origin and, in certain specific cases, to exports thereof. Regulation (EC) No 999/2001 provides that specified risk material (SRM) is to be removed and disposed of in accordance with Annex V to that Regulation. In accordance with that Annex, SRM includes the intestines from the duodenum to the rectum and the mesentery of bovine animals of all ages. The Communication from the Commission to the European Parliament and the Council – The TSE Roadmap 2: A Strategy Paper on Transmissible Spongiform Encephalopathies for 2010-2015 of 16 July 2010[39] states that any amendment of the current list of SRM referred to in Annex V to Regulation (EC) No 999/2001 (the 'list of SRM') should be based on new evolving scientific knowledge, while maintaining the existing high level of consumer protection within the Union.

No new centrally published updates on TSEs were reported in this quarter.

2.8 Veterinary residues

Commission Regulation (EU) No 37/2010 of 22 December 2009 deals with MRLs of veterinary medicinal products in foodstuffs of animal origin. The Regulation was amended in the quarter:

Commission Implementing Regulation 2015/1820[40] amended Regulation (EU) No 37/2010 to extend the permitted use of 'Diethylene glycol monoethyl ether' to poultry, there is no MRL.

Commission Implementing Regulation 2015/2062[41] amended Regulation (EU) No 37/2010 as regards the substance 'sisapronil'. The MRLs for bovine and caprine species are 100 µg kg^{-1} for muscle, 2000 µg kg^{-1} for fat, 200 µg $kg^{-1}$for liver and 100 µg $kg^{-1}$for kidney.

[37] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.302.01.0085.01.ENG
[38] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.302.01.0087.01.ENG
[39] http://ec.europa.eu/food/food/biosafety/tse_bse/docs/roadmap_2_en.pdf
[40] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.265.01.0001.01.ENG
[41] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_301_R_0003&from=EN

Commission Implementing Regulation 1390/2014[42] amended the Annex to Regulation (EU) No 37/2010, as regards the substance 'eprinomectin'. This changes the maximum residue limits (MRLs) for this substance in bovine, ovine and caprine tissues.

Commission Implementing Regulation 2015/149[43] amended the Annex to Regulation (EU) No 37/2010 as regards the substance 'methylprednisolone'. This changes the Maximum Residue Limits (MRLs) for this substance in equine and bovine tissues and products.
Commission Implementing Regulation 2015/150[44] amended the Annex to Regulation (EU) No 37/2010 as regards the substance 'gamithromycin'. This changes the Maximum Residue Limits (MRLs) for this substance in porcine and bovine tissues.

Commission Implementing Regulation 2015/151[45] amended the Annex to Regulation (EU) No 37/2010 as regards the substance 'doxycycline'. This changes the Maximum Residue Limits (MRLs) for this substance the tissues of all food-producing species.

Commission Implementing Regulation 2015/152[46] amended the Annex to Regulation (EU) No 37/2010 as regards the substance 'tulathromycin'. This changes the Maximum Residue Limits (MRLs) for this substance in ovine, caprine, porcine and bovine tissues.

Commission Implementing Regulation 2015/446[47] amended Regulation (EU) No 37/2010 as regards the substance 'barium selenate'. The Committee for Medicinal Products for Veterinary Use ('CVMP') confirmed its initial recommendation that there is no need to establish an MRL for barium selenate for bovine and ovine species. However, the CVMP concluded that because of the fact that the depletion of the substance and its residue selenium from an injection site is extremely slow, there is a risk that consumption of an injection site would lead to an intake of selenium greater than the established safe level. Therefore, to ensure that consumers' exposure to selenium is not above the established tolerable upper intake level, the CVMP recommended that barium selenate used in veterinary medicinal products should not be administered by injection.

2.8.1 Nitrofurans

Nitrofuran antimicrobial agents not authorised for use in food-producing animals in the European Union and have been the subject of a number of referee cases. EFSA published a review of nitrofurans responding to a request from the European Commission to provide a scientific opinion on the risks to human health from the presence of nitrofurans in food and whether a reference point for action (RPA) of 1.0 µg kg^{-1} for the marker metabolites is adequate to protect public health. The CONTAM Panel concluded that it is unlikely that exposure to food contaminated with nitrofuran marker metabolites at or below 1.0 µg kg^{-1} is a health concern. A scenario in which foods are considered to be contaminated with semicarbazide, from use of carrageenan as a food additive, at 1 µg kg^{-1} was used to assess whether it is appropriate to apply the RPA to foods of non-animal origin; MOEs of greater than 10^4 calculated for non-neoplastic effects do not indicate a health concern. However the CONTAM Panel recommended that there is need for a carcinogenicity study on SEM according to the current guidelines and that there is need for

[42] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.369.01.0065.01.ENG
[43] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.026.01.0007.01.ENG
[44] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.026.01.0010.01.ENG
[45] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.026.01.0013.01.ENG
[46] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.026.01.0016.01.ENG
[47] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.074.01.0018.01.ENG

information on the mechanisms underlying the genotoxic and carcinogenic effects of SEM. A paper[48] from the Government Chemist Programme was cited in the EFSA review.

2.9 Water for human consumption

Legislation on water for human consumption is noted here, whether or not regarded as 'food'.
The primary EU law on supplied water is Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption alongside Directive 2009/54/EC on the exploitation and marketing of natural mineral waters[49] (recast)[50] and Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters.[51]

Domestic implementation of the latter two is by:

- The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007 (SI 2785)
- The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007 (SSI 483)
- The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007 (SI 3165, W276)
- The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2007 (SR 420).

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015[52] amended in the quarter the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007 ("the 2007 Regulations") by implementing in relation to spring water and drinking water in a bottle, Council Directive 2013/51/Euratom laying down the requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (OJ L 296, 7.11.13, p.12). Regulation 3 makes consequential amendments to the interpretation provisions in regulation 2 of the 2007 Regulations. Regulation 4 amends regulation 16 of the 2007 Regulations to specify the monitoring and sampling requirements required by Food Authorities. Similar legislation has been enacted in Wales by the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015[53] (SI 1867, W274) and in Northern Ireland with the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2015[54] (SR 365).

Commission Directive 2015/1787[55] amended Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption. The tests to be carried out to determine quality and the frequency are described, as is the requirement for laboratories using methods accredited to ISO/IEC 17025 to carry these out.

[48] Points J, Thorburn Burns D and Walker MJ, 2015. Forensic issues in the analysis of trace nitrofuran veterinary residues in food of animal origin. Food Control, 50, 92–103.
[49] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1453734625466&uri=CELEX:32009L0054
[50] Which repeals and replaces Directive 80/777/EEC.
[51] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1453734764128&uri=CELEX:32003L0040
[52] http://www.legislation.gov.uk/ssi/2015/363/pdfs/ssi_20150363_en.pdf
[53] http://www.legislation.gov.uk/wsi/2015/1867/pdfs/wsi_20151867_mi.pdf
[54] http://www.legislation.gov.uk/nisr/2015/365/pdfs/nisr_20150365_en.pdf
[55] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.260.01.0006.01.ENG

3 Consumer choice

3.1 Food labelling

The primary legislation is now Regulation 1169/2011[56] on the provision of food information to consumers, EU FIC. A useful summary of links to the legislation and guidance has been provided by Dr David Jukes of the University of Reading.[57] Domestic implementation is effected in England by the Food Information Regulations (SI 2014 No 1855)[58], in Northern Ireland by the Food Information Regulations (Northern Ireland) 2014 (SR 2014 No 223)[59] and, in Wales the Food Information Regulations (Wales) 2014 (SI 2014 No 2303, W227)[60]. In Scotland implementation is by the Food Information Regulations (Scotland) 2014 (SSI 312)[61] which were amended in December 2015 by the Food Information (Miscellaneous Amendments) (Scotland) Regulations 2015 (SSI 410).[62] These make a set of small drafting amendments, for example clarifying aspects of the labelling of 'alcohol-free', 'dealcoholised' and 'low alcohol' drinks.

Information is available on the Commission website.[63] Guidance on nutrition labelling is also available on the Commission website.[64]

3.1.1 Country of origin labelling

The Country of Origin of Certain Meats (England) Regulations 2015 (SI 518)[65] modified certain provisions of the Food Safety Act 1990, and implemented Articles 3 to 6 and 8 of Commission Implementing Regulation (EU) No 1337/2013 regarding the provenance or country of origin of certain types of meats (fresh, chilled and frozen meat of swine, sheep, goats and poultry). Please see our July – September 2015 report for further detail.[66]

Similar legislation has been enacted in Northern Ireland through The Country of Origin of Certain Meats Regulations (Northern Ireland) 2015[67] (SR 321) and in Wales by the Country of Origin of Certain Meats (Wales) Regulations 2015[68] (SI 1591, W177).

3.1.2 Fish labelling

The Fish Labelling Regulations 2013 (in each UK country) as amended remain the principle statutory provisions. A short guide to the EU's new fish and aquaculture consumer labels has been produced (with thanks to Dr Stephen Pugh, Defra, for drawing attention to this).[69]

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56 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF
57 http://www.reading.ac.uk/foodlaw/label/links.htm
58 http://www.legislation.gov.uk/uksi/2014/1855/pdfs/uksi_20141855_en.pdf
59 http://www.legislation.gov.uk/nisr/2014/223/pdfs/nisr_20140223_en.pdf
60 http://www.legislation.gov.uk/wsi/2014/2303/pdfs/wsi_20142303_mi.pdf
61 http://www.legislation.gov.uk/ssi/2014/312/pdfs/ssi_20140312_en.pdf
62 http://www.legislation.gov.uk/ssi/2015/410/pdfs/ssi_20150410_en.pdf
63 http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/proposed_legislation_en.htm
64 http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm
65 http://www.legislation.gov.uk/uksi/2015/518/pdfs/uksi_20150518_en.pdf
66 https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2015
67 http://www.legislation.gov.uk/nisr/2015/321/pdfs/nisr_20150321_en.pdf
68 http://www.legislation.gov.uk/wsi/2015/1519/pdfs/wsi_20151519_mi.pdf
69 http://ec.europa.eu/fisheries/documentation/publications/eu-new-fish-and-aquaculture-consumer-labels-pocket-guide_en.pdf

3.1.3 Defra food labelling guidance

Defra have published guidance on the information that must be provided with food products to comply with the European Food Information to Consumers Regulation No 1169/2011 (FIC) and the Food Information Regulations 2014 (FIR).[70]

3.1.4 ECJ Court case – the *Teekanne* case

This case was a request for a preliminary ruling from the Bundesgerichtshof (Germany), and involved a fruit tea which had drawings of raspberries and vanilla flowers on the packaging even though the product did not, in fact, contain any vanilla or raspberry constituents or flavourings. It was clear from the ingredients list that the natural flavourings present had the taste of raspberry or vanilla but that those flavourings had not been obtained from raspberries or vanilla. The question referred to the court was whether, taking into account the information given in the ingredients list, this would constitute a breach of the provisions of Article 2 of 2000/13/EC relating to misleading labelling. The essence of the judgment is that the labelling of a product can be misleading as to its ingredients *even if the ingredient list itself is correct*. It will be for the German courts in the *Teekanne* case to decide whether the labelling was misleading. The ECJ approach mirrors the approach taken under section 15(4) of the Food Safety Act 1990. This provides that that the fact that a label contains an accurate statement of the composition of a food does not preclude a court from finding that it's labelling is likely to mislead a consumer.[71]

3.1.5 Organic food

All foods sold as organic must originate from growers, processors and importers who are registered with an approved certification body and subject to regular inspection. In October 2015 Defra updated the list of UK approved organic control bodies.[72]

3.2 Food Fraud

In November, the European Commission launched a dedicated IT tool, known as the Administrative Assistance and Cooperation (AAC) system to facilitate the exchange of administrative information between national authorities working to combat cross-border violations in Europe. In the wake of the horsemeat scandal of 2013, the Commission[73] developed an action plan to strengthen controls of the food supply chain. One of these measures was to set up a pan-European mechanism to ensure the rapid exchange of information between national authorities and the Commission in cases of suspected food fraud[74] cases. As a result, the European Food Fraud Network (FFN) was born and tasked with handling requests for cross-border cooperation. Each Member State has appointed a contact point to handle requests from contact points in the other Member States that form part of the network. This network has been operational since July 2013 and since its creation, the Commission has observed a marked increase in the number of exchanges from 30 in 2013 to over 90 in 2015.

Cross border cooperation helps to improve the capability of national authorities to:

- detect and prevent cross border breaches of EU food chain rules; and if necessary
- collect the information that is needed to refer a case for further investigation and to ensure appropriate enforcement action

[70] https://www.gov.uk/guidance/food-labelling-giving-food-information-to-consumers
[71] http://old.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62014CJ0195:EN:HTML
[72] https://www.gov.uk/government/publications/organic-certification-list-of-uk-approved-organic-control-bodies
[73] http://ec.europa.eu/food/safety/official_controls/food_fraud/horse_meat/index_en.htm
[74] http://ec.europa.eu/food/safety/official_controls/food_fraud/index_en.htm

The AAC system will ensure that the Food Fraud Network works even more efficiently and is able to respond more swiftly to information requests.

3.3 Caseins and caseinates

Commission Directive 2015/2203[75] covers the approximation of the laws of the Member States relating to caseins and caseinates intended for human consumption and repealing Council Directive 83/417/EEC. Compositional standards for these products are given in the Directive.

3.4 Genetically Modified Organisms

Regulation (EC) No 1829/2003 of the European Parliament and of the Council provides for the authorisation, labelling and supervision of genetically modified food and feed.[76] The Regulation was amended in the quarter.

Commission Implementing Decision 2015/2279[77] authorised the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603 × T25 (MON-ØØ6Ø3-6 × ACS-ZMØØ3-2) and Commission Implementing Decision 2015/2281[78] authorised the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 (MON-87427-7).

In November 2015 the European Commission's Joint Research Centre, JRC, published a new database[79], which contains more than 240 000 DNA sequences appearing in genetically modified organisms (GMOs). It will help to verify the presence of GMOs in food, feed and environment. To date, this new database is the largest and most comprehensive in this area.

3.4.1 Cultivation of GMOs

Commission Directive 2015/412[80] amends Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. This devolves responsibility in this matter to Member States. See our previous quarterly report[81] for further details.

3.4.2 Genetically modified animals

An interesting review paper was published on genetically modified animals. The past two decades have witnessed the rise of commercial crops that have been genetically modified for an increased suitability in extensive cultivation. Currently, a substantial body of research is being carried out in order to produce Genetically Modified (GM) animals that may similarly yield improvements in animal breeding, genetics and reproduction. The authors attempt a comprehensive review of the existing trails at animal modification with commercial applications and aimed at a deliberate release onto the market. In addition, they investigate detection and

[75] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.314.01.0001.01.ENG&toc=OJ:L:2015:314:TOC
[76] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1436450297142&uri=CELEX:02003R1829-20080410
[77] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.322.01.0058.01.ENG&toc=OJ:L:2015:322:TOC
[78] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.322.01.0067.01.ENG&toc=OJ:L:2015:322:TOC
[79] http://gmo-crl.jrc.ec.europa.eu/jrcgmoamplicons/
[80] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.068.01.0001.01.ENG
[81] https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2015

quantification options within the frame of food/feed control and traceability on the European market.[82]

3.5 Honey

The making and coming into force of the Honey (Wales) Regulations 2015[83] (SI 1507, W174) completed in the quarter the updating of domestic implementation of Council Directive 2001/110/EC relating to honey[84]. These regulations sit alongside the Honey (Scotland) Regulations 2015 (SSI 208)[85], the Honey Regulations (Northern Ireland) 2015 (SR 261)[86], and the Honey Regulations (England) 2015[87] (SI 1348) all revoking their 2003 predecessors. The Regulations regulate the use of the names "honey", "blossom honey", "nectar honey", "honeydew honey", "comb honey", "chunk honey" and "cut comb in honey", "drained honey", "extracted honey", "pressed honey", "filtered honey" and "baker's honey".

Compositional criteria and labelling are prescribed and an obligation is imposed on food authorities to enforce the Regulations. Provisions of the Food Safety Act 1990 enabling an improvement notice to be served requiring compliance with specified provisions of the Regulations are included and failure to comply with an improvement notice is an offence.
The Food Information Regulations 2014 are amended with a transitional provision in respect of food placed on the market or labelled before 24th June 2015, prohibiting an improvement notice from being served in relation to such food if it would have been compliant with the 2003 Honey Regulations.

3.6 Meat products

The Products Containing Meat etc. (England) Regulations 2014 (SI 3001/2014)[88] remain the primary domestic legislation for definitions and minimum meat content standards for certain meat products presented for sale directly to the consumer.

Similar Regulations have been enacted in Scotland with the Products Containing Meat etc. Regulations (Scotland) Regulations 2014 (SSI 289/2014)[89] which revokes the Meat Products (Scotland) Regulations 2004 (SSI 6/2004), the Meat Products (Scotland) Amendment Regulations 2008(SSI 97/2008) and regulation 18(4) of the Food Additives (Scotland) Regulations 2009(SSI 436/2009), and in Northern Ireland with the Products Containing Meat etc. Regulations (Northern Ireland) 2014[90] (SR 285/2014).

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[82] A. Lievens, M. Petrillo, M. Querci, A. Patak, Genetically modified animals: Options and issues for traceability and enforcement, Trends in Food Science & Technology, Volume 44, Issue 2, August 2015, Pages 159-176, ISSN 0924-2244, http://dx.doi.org/10.1016/j.tifs.2015.05.001. (http://www.sciencedirect.com/science/article/pii/S0924224415001223)
[83] http://www.legislation.gov.uk/wsi/2015/1507/pdfs/wsi_20151507_mi.pdf
[84] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1445979649018&uri=CELEX:02001L0110-20140623
[85] http://www.legislation.gov.uk/ssi/2015/208/contents/made
[86] http://www.legislation.gov.uk/nisr/2015/261/contents/made
[87] http://www.legislation.gov.uk/uksi/2015/1348/pdfs/uksi_20151348_en.pdf
[88] http://www.legislation.gov.uk/uksi/2014/3001/pdfs/uksi_20143001_en.pdf
[89] http://www.legislation.gov.uk/ssi/2014/289/pdfs/ssi_20140289_en.pdf
[90] http://www.legislation.gov.uk/nisr/2014/285/pdfs/nisr_20140285_en.pdf

3.7 Novel foods

The regulation of novel foods was updated in the quarter by the revocation of Regulation (EC) No 258/97[91] and its replacement by Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods[92] [...]. This Regulation also amended Regulation (EU) No 1169/2011 (the 'Food Information Regulation') and repealed Commission Regulation (EC) No 1852/2001. The new Regulation simplified the current authorisation procedures and took account of recent developments in EU law and technological progress. Food intended to be used for technological purposes (e.g. enzymes) and genetically modified food already covered elsewhere do not fall within the scope of the Regulation. The definition of novel food is clarified and updated with a reference to the general definition of food provided for in Regulation (EC) No 178/2002. One of the criteria for food to be considered a novel food continues to be the absence of use for human consumption to a significant degree within the EU before 15 May 1997, including in the Member States irrespective of the dates of their accession.

The scope of the Regulation remains similar to the previous law but now covers whole insects and their parts, and additionally categories for food with a new or intentionally modified molecular structure, food from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae, food from microorganisms, fungi or algae and food from material of mineral origin. There is also a category covering food from plants obtained by non-traditional propagating practices where those practices give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances. The definition of novel food also covers food consisting of certain micelles or liposomes.

A food should be considered a novel food where it results from a production process not used for food production within the EU before 15 May 1997, which gives rise to significant changes in the composition or structure of a food affecting its nutritional value, metabolism or level of undesirable substances.

Engineered nanomaterials should also be considered a novel food under this Regulation and the the definition of engineered nanomaterial, along with the related conferral of delegated powers to the Commission, in Regulation (EU) No 1169/2011 is deleted therefrom and replaced by provisions in this Regulation.

Vitamins, minerals and other substances intended to be used in food supplements in accordance with Directive 2002/46/EC and Regulation (EC) No 1925/2006 or in infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children, food for special medical purposes, and total diet replacement for weight control in accordance with Regulation (EU) No 609/2013 are also assessed in accordance with the rules laid down in this Regulation when they fall within the definition of novel food. As also are such vitamins, minerals or other substances that result from a production process not used for food production within the EU before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances, or where those vitamins, minerals or other substances contain or consist of engineered nanomaterials and subsequently in accordance with the relevant specific legislation.

[91] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1446024882821&uri=CELEX:01997R0258-20090807

[92] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.327.01.0001.01.ENG&toc=OJ:L:2015:327:TOC

Other provisions include on food supplements, cloned animals, traditional foods from third countries, medicinal products, post-market monitoring, and *ex-post* evaluation of the implementation of this Regulation.

Criteria for the assessment of the safety risks arising from novel foods, assessment by the European Food Safety Authority and updating the EU list are set out.

A Commission Q & A is available[93] and a list of authorisations.[94]

3.8 Olive oil

The inherent chemical composition and sensory attributes of olive products make them highly appreciated worldwide with descriptions, definitions and optional reserved terms established in Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products, (Part VIII and Annex IX). Commission Regulation (EEC) No 2568/91 defines the physico-chemical and organoleptic characteristics of olive oil and olive-pomace oil and lays down methods of assessing those characteristics. Those methods and the limit values for the characteristics of oils are regularly updated on the basis of the opinion of chemical experts and in line with the work carried out within the International Olive Council (IOC). The Regulation was amended twice in the quarter.

Commission Delegated Regulation 2015/1830[95] adjusted the the lower limit values for linoleic acid laid down in a note to the second table in Annex I to Regulation (EEC) No 2568/91 and altered from 2015 to 2016 the phased reduction of the fatty acid ethyl ester limit for extra virgin olive oil set out in that Annex. The method for the detection of extraneous vegetable oils in olive oils set out in Annex XXa to is no longer in use and has been deleted.

Commission Implementing Regulation 2015/1833[96] amended Regulation 2568/91 by updating relevant methods of analysis.

For completeness the reference to a review paper on the damage caused by olive fly, is retained from last quarter's report.[97]

3.9 Protected Names

There are 3 protection marks in the EU:

- protected geographical indication (PGI)
- protected designation of origin (PDO)
- traditional speciality guaranteed (TSG)

A list of UK protected names and a list of UK applications being considered is available.[98]

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[93] http://europa.eu/rapid/press-release_MEMO-15-5875_en.htm
[94] http://ec.europa.eu/food/safety/novel_food/authorisations/list_authorisations/index_en.htm
[95] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.266.01.0009.01.ENG
[96] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.266.01.0029.01.ENG
[97] Ricardo Malheiro, Susana Casal, Paula Baptista, José Alberto Pereira, A review of Bactrocera oleae (Rossi) impact in olive products: From the tree to the table, Trends in Food Science & Technology, Volume 44, Issue 2, August 2015, Pages 226-242, ISSN 0924-2244, http://dx.doi.org/10.1016/j.tifs.2015.04.009. (http://www.sciencedirect.com/science/article/pii/S0924224415001028)
[98] https://www.gov.uk/guidance/eu-protected-food-names-how-to-register-food-or-drink-products

3.10 Consumer attitudes

The results from the FSA's Biannual Public Attitudes Tracker for May 2015 were published. The top two food safety issues of total (i.e. spontaneous plus prompted) concern for respondents were food hygiene when eating out (37%), and the use of additives in food products (29%). The top wider food issues of total concern were the amount of sugar in food (51%), food waste (49%) and the amount of salt in food (47%).[99]

3.11 Scotch whisky

The Legal Report of the Scotch Whisky Association[100] was published in the quarter. During 2014, new proceedings were authorised in respect of 19 different brands covering Belgium, China, Curacao, Ecuador, France, Germany, India, New Zealand, the Netherlands and Scotland.[101]

4 Health and nutrition

Guidance on nutrition labelling is available on the Commission website.[102]

Regular bulletins are available from the Department of Health on EU legislation on nutrition and health claims.[103]

4.1.1 Sugar

Sugar is a topic of keen current interest and in October 2015 Public Health England published[104] a review of a broad range of measures to reduce the nation's excessive sugar consumption. The evidence review showed that action to reduce sugar consumption levels could include, but is not limited to, reducing:

- the volume and number of price promotions in retail and restaurants
- the marketing and advertising of high sugar products to children
- the sugar content in and portion size of everyday food and drink products

The review also suggested consideration of a price increase, through a tax or a levy, as a means of reducing sugar intake, although stated this is likely to be less effective than the three measures set out above.

Other conclusions from the review included setting a clear definition of high sugar foods; adopting the government buying standards for foods and catering services; delivering accredited training on diet and health to all who work in catering, fitness and leisure sectors; and continuing to raise awareness of practical steps to reduce sugar consumption.

4.1.2 Food Supplements

No new information in the quarter.

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[99] http://www.food.gov.uk/news-updates/news/2015/14268/public-attitudes-tracker-results-published
[100] http://www.scotch-whisky.org.uk/
[101] http://www.scotch-whisky.org.uk/news-publications/publications/documents/legal-report-2014/#.VjvKBNLhCCg
[102] http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm
[103] https://www.gov.uk/government/publications/nutritional-and-health-claims-legislation-bulletins-2015
[104] https://www.gov.uk/government/news/new-evidence-review-of-measures-to-reduce-sugar-consumption

5 Regulation

The Official Feed and Food Controls (England) Regulations 2009 were amended, in England, by the Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015 that came into force on 6th April 2015, see below.

5.1 Food law prosecutions database

In November 2015 FSA announced[105] the publication of a Food law prosecutions database. The database[106] gives details of local authority food hygiene and food safety prosecutions outlining where and how food businesses have breached regulations. This data is supplied on a voluntary basis by local authority officers.

5.2 Food Standards Scotland

The Food (Scotland) Act 2015[107] established Food Standards Scotland and describes the structure and function of this new food body in Scotland coming into operation on 1 April 2015.

5.3 Import controls

Commission Regulation (EC) No 669/2009 lays down rules concerning increased levels of official controls on imports of feed and food of non-animal origin when warranted by evidence of increasing threats to the food chain. The regulation is therefore periodically updated as new threats emerge or others are brought under control. In the quarter no new amendments were made.

5.4 Local authority enforcement activity

No centrally published new updates were published in the quarter. We remain open to including in this review any updates communicated by individual local authorities to the author. However see above (5.1) for Food law prosecutions database which is based on local authority activity.

5.5 Multi-Annual National Control Plan

No centrally published new updates were published in the quarter.

5.6 Food Law Code of Practice

No centrally published new updates were published in the quarter.

5.7 National sampling priorities for food

FSA has been working with UK local authorities since 2003 to support Enforcement Authority risk-based sampling and surveillance of food sold in the UK, whether it is imported or produced in the EU or UK.[108] FSA has invited recommendations for priorities for the 2016-17 National

[105] http://www.food.gov.uk/news-updates/news/2015/14644/food-standards-agency-publishes-food-law-prosecutions-database
[106] http://www.food.gov.uk/enforcement/prosecutions
[107] http://www.legislation.gov.uk/asp/2015/1/pdfs/asp_20150001_en.pdf
[108] https://www.food.gov.uk/enforcement/sampling/samplingandsurveillance

Coordinated Sampling Programme.[109] FSA in Northern Ireland published its eighth food surveillance sampling report.[110]

5.8 Community Reference Laboratories

See 'Feed Additives' below

5.9 Sugar industry

Council Regulation (EC) No 320/2006 establishing a temporary scheme for the restructuring of the sugar industry.

6 Feeding stuffs and fertilisers

The Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015 came into force on 6 April 2015. The Feed (Hygiene and Enforcement) (England) Regulations 2005, the Feed (Specified Undesirable Substances) (England) Regulations 2006, the Feed (Hygiene and Enforcement) and the Animal Feed (England) (Amendment) Regulations 2013 were revoked. Also revoked were Regulation 51 and Schedule 7 of the Official Feed and Food Controls (England) Regulations 2009 and Regulations 4, 5, 6, 7, 21, 22, and 23 and Schedule 1 of the Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010.

Thus the 2015 regulations make provisions for the appointment and qualifications of Agricultural Analysts, sampling for analysis, secondary analysis by the Government Chemist, and the form and evidential status of an Agricultural Analyst's certificate of analysis. Also dealt with are methods of analysis where the sampling has not been carried out in the course of official controls and making it an offence to tamper or otherwise interfere with a sample.

The 2015 regulations provide for the continuing execution and enforcement of Regulation (EC) No 183/2005 laying down requirements for feed hygiene and Commission Regulation (EC) No. 152/2009 laying down the methods of sampling and analysis for the official control of feed, and also make provision as to administration generally in relation to feed law, in particular so as to give effect to Regulation (EC) No 882/2004 on official controls. Part 2 of the 2015 Regulations deals with the execution and enforcement of Regulation 183/2005, which provides that almost all businesses producing, trading in or using animal feed should be either registered, or approved, by the competent authorities.

The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015[111] (SI 255) amended the Official Feed and Food Controls (England) Regulations 2009 (SI 3255) and revoked the Genetically Modified Animal Feed (England) Regulations 2004 (SI 2334), the Feed (Corn Gluten Feed and Brewers Grains) (Emergency Control) (England) (Revocation) Regulations 2007 (SI 3007) and the Animal Feed (England) Regulations 2010 (SI 2503), other than regulations 1, 2 and 14. These Regulations give effect to:

[109] https://www.food.gov.uk/news-updates/help-shape-our-policies/priorities-for-the-2016-17-national-coordinated-sampling-programme
[110] https://www.food.gov.uk/northern-ireland/news-updates/news/2015/14469/northern-ireland-food-surveillance-sampling-report-published
[111] http://www.legislation.gov.uk/uksi/2015/255/pdfs/uksi_20150255_en.pdf

- Commission Directive 82/475/EEC laying down the categories of feed materials which may be used for the purposes of labelling compound feedingstuffs for pet animals;
- Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed;
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed;
- Regulation (EC) No. 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition;
- Commission Directive 2008/38/EC establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes; and
- Regulation (EC) No. 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing certain other measures.

6.1 Dioxin testing

Regulation (EC) No 183/2005 of the European Parliament and of the Council lays down general rules on feed hygiene and processing conditions. In the quarter Commission Regulation 2015/1905[112] amended Annex II to as regards the dioxin testing of oils, fats and derived products. The amendment made the following clarifications:

a) That products derived from refined oil and feed additives authorised in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council are not covered by the definition therein.
b) The definition of fat blending excludes simple storage of consecutive batches of fats and oils without mixing them, and when blended fats are considered a compound feed and when they are feed materials.
c) Better to detect products that are clearly contaminated with dioxin at the point of entry in the feed chain, the requirements concerning dioxin monitoring set out in Annex II to Regulation (EC) No 183/2005 apply to all feed business operators placing feed on the market, including importers.
d) To achieve a representative sample incremental samples to form the aggregate sample must be taken at regular intervals, e.g. at least one incremental sample every 50 tonnes, in line with the provisions on sampling as provided for in Commission Regulation (EC) No 152/2009
e) Based on previous testing results of products derived from vegetable oils, except fatty acid distillates from physical refining and deodistillates (which appear to be deodorizer distillates), do not have a high risk for dioxin contamination and 100 % dioxin testing is no longer required for these products.

Lastly the certification that the mandatory analysis of a specific batch has been undertaken is clarified by specifying the tasks for the different feed business operators in order to clarify the responsibilities of the various actors in the feed chain.

6.2 Feed Additives

The following changes were made in feed additive legislation in the quarter.

[112] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.278.01.0005.01.ENG

Commission Regulation 2015/2294[113] amended Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of a new functional group of feed additives, "*hygiene condition enhancers*" which are substances or, when applicable, microorganisms which favourably affect the hygienic characteristics of feed by reducing a specific microbiological contamination.

Commission Implementing Regulation 2015/1747[114] corrected the Annex to Regulation (EU) No 26/2011 concerning the authorisation of vitamin E as a feed additive for all animal species. Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC. Vitamin E was subject to re-evaluation and authorised by Commission Regulation (EU) No 26/2011 (3) until 4 February 2021 as a feed additive for all animal species. Although Article 1 of Regulation (EU) No 26/2011 refers to the preparations of vitamin E that are authorised as feed additives subject to the conditions laid down in the Annex thereto, there is no reference to preparations in that Annex. This inconsistency leads the control authorities of some Member States to consider that preparations containing vitamin E are not authorised. To enable the correct interpretation of Regulation (EU) No 26/2011, it is necessary to include a reference in the Annex to that Regulation that clarifies the use and placing on the market of preparations containing vitamin E, as this was the intention when the Regulation was adopted. In addition, experience with official controls on the labelling of vitamin E showed that clarification should be brought as regards the specific name given to the additive. For example the entry "Vitamin E/all-rac-alpha-tocopheryl acetate" is replaced by "Vitamin E" or "all-rac-alpha-tocopheryl acetate" and "Vitamin E/RRR alpha tocopheryl acetate" is replaced by "Vitamin E" or "RRR alpha tocopheryl acetate".

Commission Implementing Regulation 2015/2304 authorised a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by Talaromyces versatilis sp. nov. IMI CC 378536 and Talaromyces versatilis sp. nov DSM 26702 as a feed additive for turkeys for fattening and for breeding (holder of the authorisation Adisseo France S.A.S.).

Commission Implementing Regulation 2015/2305 authorised a preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by Trichoderma citrinoviride Bisset (IM SD142) as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets, and amending Regulations (EC) No 2148/2004 and (EC) No 1520/2007 (holder of authorisation Huvepharma NV).

Commission Implementing Regulation 2015/2306 authorised L-cysteine hydrochloride monohydrate as a feed additive for cats and dogs.

Commission Implementing Regulation 2015/2307 authorised menadione sodium bisulphite and menadione nicotinamide bisulphite as feed additives for all animal species.

Commission Implementing Regulation 2015/2382[115] authorised the preparation of alpha-galactosidase (EC 3.2.1.22) produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* (CBS 120604) as a feed additive for

[113] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.324.01.0003.01.ENG&toc=OJ:L:2015:324:TOC
[114] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.256.01.0007.01.ENG
[115] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.332.01.0054.01.ENG&toc=OJ:L:2015:332:TOC

laying hens and minor poultry species for laying (holder of the authorisation Kerry Ingredients and Flavours).

6.2.1 Community and National Reference Laboratories

Regulation (EC) No 1831/2003 deals with application for, and authorisation of, feed additives in animal nutrition with detailed rules in Regulation (EC) No 1831/2003 including the duties and tasks of the Community Reference Laboratory ('CRL'). In October 2015 Commission Implementing Regulation 2015/1761[116] amended Regulation 378/2005 as regards the Community Reference Laboratory reports, fees and the feed additive national reference laboratories, including LGC, listed in Annex II thereto.

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[116] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.257.01.0030.01.ENG