



Food and feed law:

**Compendium of UK food and feed legislation
with associated context and changes during
October – December 2017**

Government Chemist Programme Report



Department for
Business, Energy
& Industrial Strategy

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UK food and feed legislation & changes during October - December 2017

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Introduction to 'Food and feed law' review series

This is the third in a series of quarterly reports produced under the Government Chemist Programme 2017–2020. The reports provide a compendium of UK food and feed law of interest to the Government Chemist, Public Analysts and those working primarily in food and feed standards. The aim is to provide regular updates, to ensure contextual awareness and assist in the interpretation of chemical measurement data. The reports group legislation into six broad categories; although updates in all the categories may not occur for 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.

In keeping with the changed emphasis that withdrawal from the European Union is likely to bring, the reports now attempt to include developments in Codex (*Codex Alimentarius*) and other major trading blocs such as the US. International and European measures are cited along with the implementing domestic legislation. Potentially temporary and local measures, such as prohibition legislation for shellfish harvesting areas, have not been recorded.

Please note – key information to maintain a permanent introduction to relevant legislation in certain areas is carried forward from previous reports, however legislation in force and made prior to October 2017 may 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.

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 and recitals that accompany legislation. Hyperlinks in the document were accessed and available at the date of this report. The reports are not indexed but the Table of Contents is extensive.

A companion series on standards published by the European standardisation organisation, CEN, some of which are relevant to chemical measurement in support of regulation, is also published on the [Government Chemist website](#).

For successive quarterly reports new entries are identified by a side bar. Redundant material will be progressively removed but may be found in the previous editions.

Summary

The summary updates our legislation review with developments in food and feed law and related scientific and regulatory issues for the period from October to December 2017. Cross cutting issues are mentioned firstly followed by technical updates in alphabetical order by subject. For further information and references to original sources please see the relevant section of the main report.

Cross-cutting issues

Exiting the EU

Although there were significant political developments in December 2017 and the Department for Exiting the European Union's rolling list of events and policy website was regularly updated no new legislative changes were noted in the period. The European Institutions published, on 29 December 2017, a statement on EU legislative priorities for 2018-2019 however no specific mention of food or feed was included. (Section 1.1)

Regulation and enforcement

A significant development in December 2017 was a proposal, in a paper endorsed by the FSA Board on surveillance strategy, for a formal review of the UK official control laboratory system in its entirety, to include the role of the Laboratory of the Government Chemist as the UK referee laboratory for food and feed. The latest FSA 'Regulating our Future', RoF, newsletter included a report from a feasibility study into how Primary Authority schemes might work, the findings of work on how small and medium sized enterprises view regulation, development of the target operating model for RoF, and input from a Trading Standards Officer on food standards aspects of RoF. (Section 1.3)

Codex and FAO

A new Codex website was launched in December 2017 (Section 1.2) and the Food and Agriculture Organization of the United Nations (FAO) 'State of Food and Agriculture 2017' was published in November 2017. It shows how an "agroterritorial" planning approach, focused on connecting cities and towns and their surrounding rural areas, combined with agro-industrial and infrastructure development can generate income opportunities throughout the food sector and underpin sustainable and inclusive rural transformation. (Section 1.12)

Technical updates

Acrylamide

In November 2017 Commission Regulation (EU) 2017/2158 established mitigation measures and benchmark levels for the reduction of the presence of the carcinogen acrylamide in food. The mitigation approaches include implementation of good hygiene practice and application of hazard analysis and critical control point (HACCP) principles. Procedures are set out, and benchmark concentrations have been developed, to gauge the effectiveness of mitigation through sampling and analysis which is required of food businesses. The analytical method performance characteristics are laid down. If the analytical result, corrected for recovery *but not taking into account the measurement uncertainty*, indicates that a product has exceeded the benchmark level, or contains acrylamide at a level higher than anticipated the business must carry out a review of the mitigation measures applied. The benchmark acrylamide concentrations range from 40 µg kg⁻¹ for certain baby foods, 500 µg kg⁻¹ for ready-to-eat chips (French fries), 750 µg kg⁻¹ for potato crisps, to 850 µg kg⁻¹ for instant (soluble) coffee. The mitigation measures in brief include,

for example for chips, the use of potato varieties with lower sugar content and storage of potatoes at a temperature higher than 6 °C, washing the potato chips prior to frying, and frying temperatures below 175 °C. (Section 2.3.1)

Animal feed

Commission Regulation (EU) 2017/2229 of 4 December 2017 amended Annex I to Directive 2002/32/EC on undesirable substances in animal feed as regards maximum levels for lead, mercury, melamine and deoquinone. In Regulation (EC) No 767/2009, on the placing on the market and use of feed, tolerances for analytical constituents and feed additives in feed materials and compound feed, and labelling particulars for feed materials and compound feed for food-producing and non-food producing animals were amended. (Section 6.1)

Case law

Article 28 of Regulation 834/2007 imposes conditions of notification to the competent authorities and submission to a control body on any operator who trades in organic products from a third country. However Member States may exempt operators who (with provisos) sell products *directly to the final consumer or user*. The meaning of the latter phrase was tested before the European Court, which ruled that it must be interpreted as meaning that, in order for products to be regarded as being sold 'directly', within the meaning of the relevant provision, to the final consumer or user, it is necessary for the sale to occur in the presence of both the business operator or his sales personnel and the final consumer. The author of the present report wonders if this may have implications for the interpretation of 'prepacked for direct sale' in Regulation 1169/2011 (Food Information to Consumers)? (Section 3.1.5)

In a judgment of the European Court (Third Chamber) of 13 September 2017 (Case C-111/16) the court reaffirmed that Member States cannot adopt interim emergency measures on GMOs solely on the basis of the 'precautionary principle', without appropriate conditions being satisfied (... likely to constitute a serious risk to human health, animal health or the environment). (Section 3.4)

Endocrine-disrupting chemicals

The growing interest in the possible health threat posed by endocrine-disrupting chemicals in the environment, food, and consumer products led to Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 which set out scientific criteria for the determination of endocrine-disrupting properties. A substance shall be considered as having endocrine-disrupting properties with respect to humans or non-target organisms, where it meets criteria set out in the Regulation. These include if it shows a defined adverse effect in an intact organism or its progeny, has an endocrine mode of action and the adverse effect is a consequence of this as assessed by defined scientific evaluation. (Section 2.5)

Food additives

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) published safety evaluations of allura red, carob bean gum, pectin, quinoline yellow, rosemary extract, steviol glycosides, tartrazine xanthan gum and certain flavourings. (Section 2.4)

Food allergy

The convicted owner of the restaurant in which was caused the death by anaphylaxis of Paul Wilson appealed his conviction and sentence. The appeal in respect of both conviction and sentence was dismissed. AOAC INTERNATIONAL (formerly Association of Official Analytical Chemists), published a special edition of its journal, J AOAC International, on food allergens. The

edition contained three papers from the Government Chemist. The edition is open access and is available on the J AOAC International website. In December 2017 the Commission gave further guidance on Annex II to Regulation 1169/2011 dealing with ways of providing allergen information for pre-packed foods. (Section 2.1)

Food fraud

The JRC monthly summary on food fraud and adulteration was published in October 2017 and noted issues with wine, seafood, herbs and honey (Section 1.7). The issue of certain dual quality products can be a source of concern when the different composition of identically branded goods has the potential to mislead the consumer. In September 2017 the Commission issued a notice on the application of EU food and consumer protection law to these issues (Section 3.2). The Intentional Adulteration Rule mandated by the FDA (Food and Drug Administration) Food Safety Modernization Act (FSMA) requires food facilities, with some exceptions, to address hazards that may be introduced with the intention of causing wide-scale harm to public health. (Section 5.1)

Food hygiene

A very long running saga concluded in October 2017 when the FSA announced that infants, children, pregnant women and elderly people can now safely eat raw or lightly cooked eggs that are produced under the British Lion Code of Practice. The World Health Organization (WHO) has published guidance on the selection and application of methods for the detection and enumeration of human-pathogenic halophilic vibrio spp. in seafood. The European Commission published the 'European Guide for Good Hygiene Practices in the production of artisanal cheese and dairy products' authored by the Farmhouse and Artisan Cheese & Dairy Producers European Network (FACE network). This is one of a suite of guidance available on the Commission website. (Section 2.15)

Free range eggs

Commission Delegated Regulation (EU) 2017/2168 of 20 September 2017 amended Regulation (EC) No 589/2008 on marketing standards for free range eggs where hens' access to open air runs is restricted. (Section 3.3.5)

Genetically modified organisms

Pursuant to Regulation (EC) No 1829/2003 four soybean and three oilseed rape GMOs were authorised and one maize GMO authorisation was renewed on 21 December 2017. (Section 3.4)

Import controls

Commission Regulation (EC) No 669/2009, which covers 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, was again updated. A derogation was introduced to allow sampling at the place of destination of highly perishable products, or products in packaging for which sampling would inevitably cause a serious risk to food safety or in the product being damaged to an unacceptable extent. There were enhanced controls on pesticides in consignments of peppers from India and Pakistan, it was clarified that increased controls of pistachios from the United States (for aflatoxins) also included roasted pistachios, and that peppers from Thailand and Vietnam (for pesticides) includes frozen peppers. The chemical hazards in Regulation 669/2009 currently focus on aflatoxins, ochratoxin A, pesticides residues, Sudan dyes, and sulphites.

Marine biotoxins

Commission Regulation (EU) 2017/1980 of 31 October 2017 confirmed the reference method for paralytic shellfish poison (PSP) as the so-called Lawrence method as published in AOAC Official Method 2005.06 (pre-column oxidation liquid chromatography with fluorescence detection). Commission Implementing Regulation (EU) 2017/2369 of 18 December 2017 extended to 31 December 2021 the ban on importation of live and chilled bivalve molluscs from Turkey and testing for *Escherichia coli* and marine biotoxins in all consignments of frozen bivalve molluscs. (Section 2.8)

Mercury

The Control of Mercury (Enforcement) Regulations 2017 were made in December 2017, providing for the enforcement of Regulation (EU) 2017/852 on Mercury, to fill gaps in existing EU mercury legislation and enable ratification of the Minamata Convention on Mercury. This Convention is designed to protect global human health and the environment from the adverse effects of exposure to mercury and includes restrictions on the import and export of mercury, requirements for the phasing out of the use of mercury in a number of products and processes, as well as measures on interim storage of mercury and its disposal once it becomes waste. (Section 1.14)

Novel Foods

Novel foods and novel food ingredients are regulated by Regulation (EC) No 258/97 replaced on 1 January 2018 by Regulation (EU) 2015/2283 with a streamlined authorisation procedure. Domestic implementation of the new Regulation proceeded with statutory instruments in Wales and Scotland. Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 lists EU novel foods authorised to date together with the conditions under which the novel food may be used, including maximum levels if applicable, any specific labelling requirements and any other requirements. Five novel food authorisations were published in the period: an extension of use of yeast beta-glucans, an extension of use of Chia seeds and authorisation of 2'-fucosyllactose, an oligosaccharide found in milk, synthetic hydroxytyrosol, found naturally in olives and olive oil, and synthetic N-acetyl-D-neuraminic acid, NANA, also known as sialic acid, found naturally in human milk as an endogenously produced monosaccharide. Regulations were made on the administrative and scientific requirements for applications for novel food authorisation (Section 3.6). Two novel foods for use only in food supplements were authorised, taxifolin a flavonoid also known as dihydroquercetin, and *Calanus finmarchicus* oil, from the marine zooplankton *C. finmarchicus* harvested in the Norwegian Economic Zone. (Section 4.5)

Organic food

Provisions on imports of organic products from third countries, inclusion of certain non-organically reared pullets and non-organic protein feed in designated organic products, and an agreement between the EU and the Republic of Chile on trade in organic products were made. The meaning of the phrase *directly to the final consumer or user* in the sale of organic products was tested before the European Court. (Section 0)

Plastic microbeads

The prohibition of the use of microbeads was well-publicised. Public Analysts may be called upon to comment on what constitutes a 'microbead' which the Environmental Protection (Microbeads) (England) Regulations 2017 defines as any water-insoluble solid plastic particle of less than or equal to 5 mm in any dimension. (Section 1.15)

Products of animal origin

New rules on harvesting echinoderms (e.g. sea cucumbers) outside classified production areas were introduced. Commission Regulation (EU) 2017/1981 of 31 October 2017 amended Annex III to Regulation (EC) No 853/2004 as regards temperature conditions during transport of meat. (Section 2.10)

Protection of geographical indication

Council Decision (EU) 2017/1912 of 9 October 2017 established Agreement between the EU and Iceland on the protection of geographical indications for agricultural products and foodstuffs. (Section 3.1.7)

Psychoactive substances

Directive (EU) 2017/2103 of 15 November 2017 amended Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug', and Regulation (EU) 2017/2101 of the same date brought in improved information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances. Also, in November 2017 the Court of Appeal (Criminal Division) heard appeals against convictions of possessing a psychoactive substance, nitrous oxide, on the grounds that nitrous oxide is a medicinal product, exempt in the Psychoactive Substances Act. The appeals were dismissed. (Section 2.17)

Radioactivity

Commission Implementing Regulation (EU) 2017/2058 of 10 November 2017 further relaxed Regulation (EU) 2016/6 on the import of feed and food from Japan following the accident at the Fukushima nuclear power station on foot of data gathered by the Japanese authorities and import controls at the EU border. (Section 2.11)

Statistics

The Defra (Department for Environment, Food and Rural Affairs) Food Statistics Pocketbook Summary was published November 2017 and provides comprehensive economic and trend data on UK food. (Section 1.9)

Total diet replacement for weight control

After an abortive attempt to introduce specific compositional and information requirements for total diet replacement for weight control in June 2017, this was achieved in October 2017 by Commission Delegated Regulation (EU) 2017/1798 which sets out (a) compositional requirements, (b) requirements for labelling, presentation and advertising and (c) notification requirements for placing the product on the market. Compositional requirements include vitamins and minerals, and protein quality in terms of the amino acid profile. (Section 4.2.1)

Water

The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations were updated in Northern Ireland, Wales and Scotland. The latter date from 2007 with a series of amendments and this author suggests stand in need of consolidation. Public and Private Water Supplies Regulations were amended in Northern Ireland, Scotland and Wales. (Section 2.16)

Wine

The use of filter plates containing zeolites γ -faujasite to adsorb haloanisoles and the treatment of wine with potassium polyaspartate were authorised (Section 2.4.6). Regulations mainly

concerning the common agricultural policy were updated but this included Regulation 1308/2013 on the common organisation of the markets in agricultural products which was amended to allow the upper limit for the total alcoholic strength to exceed 15 % volume for wines with a protected designation of origin which have been produced as detailed in the amendment. The measure also made minor changes for years when climatic conditions have been exceptionally unfavourable for wine (Section 3.3.4). An increase was allowed of the limits for the enrichment of wine produced using the grapes harvested in 2017 in certain wine-growing regions of Germany and in all wine-growing regions of Denmark, the Netherlands and Sweden owing to exceptionally unfavourable climatic conditions. (Section 3.3.10)

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1 Cross-cutting issues

1.1 Exiting and new partnership with the European Union

Background information is at Section 1.1 of our previous reports.¹⁻³

The Department for Exiting the European Union maintains a rolling list of events and policy.⁴ The European Union (Withdrawal) Bill (known as the Repeal Bill) passed its Second Reading in the House of Commons on 7 September 2017. The Bill will move to Committee Stage in the coming weeks as it continues its passage through Parliament.

The European Commission also maintains a rolling list of events and papers.⁵

The European Institutions published, on 29 December 2017, a statement on EU legislative priorities for 2018-2019. These covered security, migration, jobs, growth and investment, social security, a connected digital single market, energy and the European Citizens' Initiative. The statement also referred to common European values, a robust, open and rules-based trade policy, tackling tax fraud, tax evasion and tax avoidance, data protection, digital rights and ethical standards while capturing the benefits and avoiding the risks of developments in artificial intelligence and robotics.⁶

1.2 Codex Alimentarius

The *Codex Alimentarius*, or 'food code', is the global reference point for consumers, food producers and processors, national food control agencies and the international food trade.⁷ A 2016 publication, 'Understanding Codex'⁸ is a valuable guide to its operation. The core function of Codex is the development of international standards. Links to recent sessions of Codex committees in a variety of commodity areas are provided in Section 1.2 of our April – June 2017 report.⁹

The 40th Session of the Codex Alimentarius Commission was held from 17-22 July 2017 in Geneva. The decisions included:

- Guidelines on nutrition labelling (nutrition information on food packaging for consumers)
- Code of hygienic practice for fresh fruits and vegetables
- Maximum residue limits for more than 20 pesticides in various foods
- Maximum levels of certain food additives
- Maximum level of lead in processed fruits and vegetables
- Maximum residue limits in meat for veterinary drugs (ivermectin, lasalocid sodium and teflubenzuron)
- Code of practice for the prevention and reduction of arsenic contamination in rice
- Standards for cumin, thyme, & black, white, green pepper

¹ <https://www.gov.uk/government/publications/food-and-feed-law-update-january-march-2017>

² <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2017>

³ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-july-to-september-2017>

⁴ <https://www.gov.uk/government/policies/brexit>

⁵ https://ec.europa.eu/commission/brexit-negotiations_en

⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.446.01.0001.01.ENG&toc=OJ:C:2017:446:TOC

⁷ <http://www.fao.org/fao-who-codexalimentarius/home/en/>

⁸ <http://www.fao.org/3/a-i5667e.pdf>

⁹ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2017>

New work proposed included the Codex task force on antimicrobial resistance, establishing maximum levels of mercury in fish, guidelines for risk analysis of chemicals inadvertently present in food at low levels, and a new code of practice for reduction of chemical contaminants in refined oils and products made with refined oils such as palm oil.¹⁰

Details of other recent Codex meetings and reports are available [here](#).

A new Codex website was launched in December 2017 with dedicated thematic pages on the broad scope of the Codex programme in areas such as contaminants, nutrition, antimicrobial resistance and biotechnology, allowing new visitors to begin to understand the work and impact of the food safety standards Codex develops. Six new regional web pages have been designed to promote specific Codex activities taking place locally from the South West Pacific through Asia, Africa, Europe, the Near East and on to Latin America and the Caribbean. A redesigned meetings page shows upcoming sessions at a glance. The archives contain the complete history of meetings and a new [timeline](#) traces the birth and development of the Codex Alimentarius Commission. Newly designed search tools aim to be easier to use and publications have a new landing page and can be downloaded directly from the website.

1.3 FSA Food regulation – ‘Regulating our Future’, ‘RoF’

The FSA published on 19 July 2017 a key paper¹¹ on the fundamental redesign of the FSA’s regulatory role and of the way in which regulation is delivered. The paper details the changes the FSA wants to make including:

- An enhanced system of registration for businesses, better to identify and manage risk with the aim to create a hostile environment for those businesses that do not proactively register;
- Segmenting businesses in a better way using a range of risk indicators based on wider information about the business, including the information gathered at the point of registration and from other sources;
- Introduction of more options for businesses to prove compliance. Depending on how robust the information that businesses share is, including their past performance, FSA will set the frequency and type of inspection activity they face. Businesses with a good history of compliance should face a lower burden from regulation, and free local authority resources to target the businesses that present the greatest risk to public health;
- FSA will continue to ensure the Food Hygiene Rating Scheme is sustainable and display becomes mandatory in England as it is in Wales and Northern Ireland.

Background to RoF is in Section 1.3 of our April to June report.¹²

A significant development in December 2017 was a proposal, in a paper endorsed by the FSA Board on surveillance strategy, for formal review of the UK official control laboratory system in its entirety, to include the role of the Laboratory of the Government Chemist as the UK referee laboratory for food and feed. The relevant text of the Board paper reads as follows.¹³

6. Laboratories

¹⁰ <http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CAC&session=40>

¹¹ <https://www.food.gov.uk/news-updates/news/2017/16363/fsa-publishes-plans-future-regulation>

¹² <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2017>

¹³ <https://www.food.gov.uk/about-us/our-board/meetings>

6.1. The UK official control laboratory network plays a major part in providing analytical data as part of the wider-evidence base which supports the ‘scan’ and ‘spot’ stages of the surveillance cycle (Figure A1 in Annex A). Data and intelligence generated through the official control laboratory network also plays a major part in the Agency being able to ‘evaluate’ whether interventions undertaken have been successful.

6.2. The UK National Control Plan provides a general overview of the current official control network. In summary, the UK official control laboratory network is segmented and complex and was last formally reviewed, in part, by Alan Turner OBE in 1998 (Public Analyst Arrangements in England and Wales). The Elliott review into the integrity and assurance of food supply networks also made recommendations in relation to the work of public analysts on food authenticity and fraud, which is one element of the current UK official control laboratory system.

6.3. Significant work has been undertaken by Defra, DH and the FSA since 2014 to support the creation of a public-sector laboratory network, now operating as the Association of Local Authority Public Analyst Laboratories (ALAPAL).

6.4. Since the creation of the FSA there has never been a formal external review of the UK official control laboratory system in its entirety, encompassing the roles of public analysts, food examiners, agricultural analysts, national reference laboratories and the role of the Laboratory of the Government Chemist as the UK referee laboratory for food and feed. Over the years analytical techniques typically used for official control purposes have become more digital/instrumental in nature and there is no longer a clear demarcation between the current official control disciplines. In the build-up to the UK exiting the EU there is an opportunity to review the current system (taking into consideration, for example, capacity, capability, scale and surge, independence, competence, quality) such that the UK has a more joined-up, less-segmented, efficient and sustainable official control laboratory network thereby enabling the FSA to be an excellent, accountable, modern regulator.

6.5. We are discussing the case and options for such a review with FSS, PHE and BEIS. The views of the Board at this stage will inform and support these discussions

A series of RoF newsletters is published by FSA.¹⁴ The sixth edition included a report from a feasibility study into how Primary Authority schemes might work in the future and the findings of work on how small and medium sized enterprises view regulation. The seventh edition included news about the segmentation working group, which supports the development of the target operating model for ROF, an interview with Diane Cook who chaired the last of the current sessions of the consumer panel and input from Aaron Esler a Trading Standards Officer on food standards aspects of RoF. A Parliamentary Reception in October 2017 enabled FSA to discuss RoF with stakeholders.

1.4 Regulation (EU) No 2017/625 on official controls

Regulation (EC) No 882/2004 *on official controls* was replaced by Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 *on official controls and other*

¹⁴ <https://www.food.gov.uk/about-us/about-the-fsa/regulating-our-future/regulating-our-future-newsletter>

official activities.^{15, 16} Background to this was given in a previous edition of this report.¹⁷ Regulation 2017/625 supplements Regulation (EC) No 178/2002¹⁸ and, stemming from the Treaty on the Functioning of the European Union,¹⁹ aims for a high level of:

- Protection of human, animal and plant health and of the environment via veterinary and phytosanitary measures;
- Consumer protection in the internal market;
- Animal welfare along the agri-food chain.

A fuller discussion of Regulation (EU) 2017/625 is at Section 1.4 of our April to June report.²⁰

1.5 Antimicrobial resistance, AMR

It has been estimated that the global impact of AMR could be 10 million deaths annually by 2050, and cost up to US \$100 trillion in cumulative lost economic output.²¹ An FSA commissioned research report confirmed the need for extra surveillance of AMR in food at retail level, to support the wider programme of work currently underway across government to help reduce levels of AMR. The research was released ahead of a *Codex Alimentarius* working group on AMR held in London in late 2016.²² The working group was organised by the FSA and chaired by the UK, USA and Australia. It was the first step in this new area of work, and set terms of reference for the intergovernmental task force that followed.²³ On 17 February 2017 the Codex Secretariat published²⁴ the report of the working group on AMR mentioned above. The report is available [online](#) as a working document of the 40th Codex Alimentarius Commission which took place in Geneva in July 2017 (see Section 1.2). Also of interest is the FAO-led Multi-stakeholder Partnership for Capacity Development for Feed Safety²⁵ and FAO has produced a useful report on the 'drivers, dynamics and epidemiology of antimicrobial resistance in animal production'.²⁶

The European Commission published in July 2017 EU Guidelines for the prudent use of antimicrobials in human health, (2017/C 212/01).²⁷

1.6 Emerging risks

The Emerging Risks Exchange Network, EREN, has been referred to in previous reports^{28, 29} and regularly updates outline emerging risks in brief meeting reports.³⁰

¹⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.095.01.0001.01.ENG&toc=OJ:L:2017:095:TOC

¹⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1505320836050&uri=CELEX:02017R0625-20170407>

¹⁷ Walker M. J. (2017) Food and Feed Law: legislation review, January – March 2017, Section 5, pp 45 – 48,

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/617645/Foodfeedlaw_Jan-Mar_2017_v3.pdf

¹⁸ Latest consolidated version at time of writing that of 30.06.2014: <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498146098818&uri=CELEX:02002R0178-20140630>

¹⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT>

²⁰ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2017>

²¹ Prof Guy Poppy, FSA Chief Scientific Adviser's Science Report Issue four: Antimicrobial resistance in the food supply chain https://www.food.gov.uk/sites/default/files/csa-amr-report_0.pdf

²² <http://www.fao.org/fao-who-codexalimentarius/roster/detail/en/c/456452/>

²³ <https://www.food.gov.uk/news-updates/news/2016/15746/fsa-publishes-review-of-antimicrobial-resistance-evidence>

²⁴ <http://www.fao.org/fao-who-codexalimentarius/roster/detail/en/c/471647/>

²⁵ <http://www.fao.org/fao-who-codexalimentarius/roster/detail/en/c/470458/>

²⁶ Food and Agriculture Organization. Drivers, dynamics and epidemiology of antimicrobial resistance in animal production – Wall B. A, <http://www.fao.org/3/a-i6209e.pdf>

²⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.212.01.0001.01.ENG&toc=OJ:C:2017:212:TOC

²⁸ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-january-to-march-2016>

²⁹ <https://www.gov.uk/government/publications/food-and-feed-law-update-january-march-2017>

³⁰ <https://www.efsa.europa.eu/en/topics/topic/emergingrisks>

1.7 Food fraud/food crime

Food fraud is a dishonest act or omission in the production or supply of food intended for personal gain or to cause loss to another party. Food fraud becomes food crime when its scale is more complex or likely to be seriously detrimental to consumers, businesses or the overall public interest, or when organised criminals are involved. The criminal activity may be cross-regional, national or international. The concept of 'food crime' was highlighted by the Elliott Review which led to the establishment of the FSA's National Food Crime Unit,³¹ NFCU. Food Standards Scotland (FSS) independently established a Scottish Food Crime and Incidents Unit (SFCIU).³²

In 2016 the NFCU launched 'Food Crime Confidential', a reporting facility where anyone with suspicions about food crime can report them safely and in confidence, over the phone and through email. The facility is particularly targeted at those working in or around the UK food industry.³³ This followed the 2016 review of the NFCU carried out by FSA under the oversight of an independent steering group, which recommended NFCU should be given additional powers and resources to boost its ability to tackle food crime and protect consumers.³⁴ The NFCU launched an industry guide on 31 October 2016 explaining the NFCU's role and how it can support industry, as the first step in building a meaningful two way dialogue between the NFCU and the food, drink and feed industry.³⁵

Science and technology company Campden BRI has been chosen to provide technical and administrative support to the Food Industry Intelligence Network, FIIN, by curating a database to collect anonymised industry data on food authenticity testing. They will analyse the data producing regular reports for the FIIN members. Campden BRI will also be responsible for managing the FIIN membership and organising FIIN events. FIIN was established by industry technical leaders to share intelligence on food authenticity. FIIN currently has 21 members in the UK including major retailers, manufacturers and food service companies.³⁶

In early 2016 the FSA published³⁷ the first assessment of food crime in the UK, the Food Crime Annual Strategic Assessment (FCASA). Readers are referred to the FCASA for a list of strategic food crime priorities.

The United Nations Office on Drugs and Crime has published a 'World wildlife crime report 2016: Trafficking in protected species', which includes a case study on caviar in the seafood industry.³⁸ The report as a whole provides good background context for a topic in which molecular biology has a significant role to play.

The European Commission IT tool to facilitate the exchange of administrative information between national authorities working to combat cross-border violations in Europe – known as the Administrative Assistance and Cooperation (AAC) system – was described in a previous report. In the wake of the horsemeat episode of 2013, the Commission³⁹ also 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

³¹ <https://www.food.gov.uk/enforcement/the-national-food-crime-unit>

³² <http://www.foodstandards.gov.scot/food-crime>

³³ <https://www.food.gov.uk/news-updates/news/2016/15226/food-crime-confidential-launch>

³⁴ <https://www.food.gov.uk/news-updates/news/2016/15679/nfcu-review-published>

³⁵ <https://www.food.gov.uk/news-updates/news/2016/15642/nfcu-launches-industry-guide>

³⁶ <https://www.campdenbri.co.uk/pr/food-fraud.php>

³⁷ <https://www.food.gov.uk/news-updates/news/2016/15017/the-food-standards-agency-fsa-has-today-published-the-first-assessment-of-food-crime-in-the-uk>

³⁸ https://www.unodc.org/documents/data-and-analysis/wildlife/World_Wildlife_Crime_Report_2016_final.pdf

³⁹ http://ec.europa.eu/food/safety/official_controls/food_fraud/horse_meat/index_en.htm

and the Commission in cases of suspected food fraud.⁴⁰ The AAC system will ensure that the Food Fraud Network works even more efficiently and is able to respond more swiftly to information requests.

In May 2016 the FDA Food Safety Modernization Act (FSMA) final rule was publicised aimed at preventing intentional adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply. Such acts, while not likely to occur, could cause illness, death, economic disruption of the food supply if mitigation strategies are not in place. Rather than targeting specific foods or hazards, this rule requires mitigation (risk-reducing) strategies for processes in certain registered food facilities and a useful set of documents accompanies the fact sheet on this issue.⁴¹

A resolution of the European Parliament on food fraud, begun in 2014, has been debated and was published in December 2016. The Parliament noted its concern and has proposed a series of measures.⁴²

Although not related to food, a recent report may be of interest because it measures the direct, economic effects of counterfeiting on (a) consumers, (b) retail and manufacturing industry and (c) governments in the United Kingdom. It covers the impact of fake products imported into the UK, and the impact of the global trade in fake products on UK intellectual property rights holders.⁴³

The authenticity of marine species often depends on the correct taxonomic identification of species for which DNA profiles are uploaded to public databases such as the Barcode of Life Data System (BOLD)⁴⁴ and the National Center for Biotechnology Information (NCBI) GenBank⁴⁵ hence we welcome the publication of 'Marine species biological data collection manual: an illustrated manual for collecting biological data at sea'.⁴⁶

The JRC monthly summary on food fraud and adulteration was published in October 2017 and noted issues with wine, seafood, herbs and honey.⁴⁷

See also Section 3.3.3 on honey fraud detection.

1.8 Incidents

In June 2016 the FSA published⁴⁸ its annual report of 2015 food incidents. It showed that in 2015, the FSA and FSS were notified of, investigated and managed 1,514 food, feed and environmental contamination incidents in the UK. The four largest contributors in 2015 were: pathogenic micro-organisms, allergens (which increased from 89 to 206), chemical contamination and residues of veterinary medicinal products.

⁴⁰ http://ec.europa.eu/food/safety/official_controls/food_fraud/index_en.htm

⁴¹ <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm>

⁴² Food crisis, fraud in the food chain and the control thereof, European Parliament resolution of 14 January 2014 on the food crisis, fraud in the food chain and the control thereof (2013/2091(INI)) http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.482.01.0022.01.ENG&toc=OJ:C:2016:482:TOC

⁴³ <http://www.oecd.org/unitedkingdom/trade-in-counterfeit-products-and-the-uk-economy-9789264279063-en.htm>

⁴⁴ Ratnasingham, S. and Hebert, P.D.N. (2007) BOLD: The Barcode of Life Data System. Molecular Ecology Notes. <http://www.boldsystems.org/> www.barcodinglife.org

⁴⁵ National Center for Biotechnology Information, U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda MD, 20894 USA. <http://www.ncbi.nlm.nih.gov/>

⁴⁶ <http://www.fao.org/3/a-i6353e.pdf>

⁴⁷ <https://ec.europa.eu/jrc/en/research-topic/food-authenticity-and-quality>

⁴⁸ <http://www.food.gov.uk/news-updates/news/2016/15190/fsa-annual-report-of-incidents-2015-published>

FSA has published a series of within year lists of incidents.⁴⁹ Over the three month period from July – September 2016, FSA issued 54 food notices, of which 30 were allergy alerts, with the top three undeclared allergens being egg, nuts and mustard. The latest available quarterly update is that of 31 January 2017 which covered October – December 2016.⁵⁰ Over the three month period, FSA issued 34 food notices, of which 17 were allergy alerts, with the top three undeclared allergens being milk, nuts and [cereals containing] gluten.

1.9 Data science

International trade in agricultural and food products is more complex than other trade – regulations are stricter, paperwork more cumbersome and logistics more complex – mainly for safety and authenticity reasons. Detailed information exchange alongside the movement of goods in a supply chain is critically important and progress has been made in electronic, paperless, systems.

In April 2017 FSA published⁵¹ a report on data science from its Chief Scientific Adviser Professor Guy Poppy, his sixth Science Report. Advances in data science techniques are making the large amounts of data collected by the FSA and food businesses more valuable. The report shows how the Agency is bringing together a wide range of data, from the complex food industry ‘ecosystem’ to social media and consumer preferences, to explore ways that it can meet its regulatory responsibilities going forward and become data-driven. This also includes working in partnership on research with University College London’s Big Data Institute and the Office for National Statistics amongst others, to get the best value from data as well as supporting FSA objectives and learning with and from others. Data Science is feeding into the implementation of the Agency’s innovative new Surveillance Strategy and the ‘Regulating our Future’ change programme which is redesigning the FSA’s regulatory role.

A United Nations publication outlines a framework for integrated agri-food information management, taking into account the functional needs of various stakeholders along the supply chain. The benefits as well as challenges involved in developing a comprehensive system are discussed. Some examples of existing paperless systems – which are considered good practices for agri-food trade – are also included together with the list of relevant international standards to be taken into account when implementing the systems. Practical recommendations for, and milestones in the enhancement of agri-food information systems for trade facilitation are provided, including a recommendation to develop a Single Window for Agri-food Trade (SWAT). This publication is aimed mainly at government officials involved in overseeing and making policies related to agri-food trade. It is also relevant to the private sector (both existing and potential traders), associations and any agri-food supply-chain stakeholders interested in making agri-food trade both safer and more efficient. This policy guide builds on the series of technical and legal guides produced by UNNExT to facilitate paperless trade implementation.⁵² Previous guides are also available.⁵³

The Defra Food Statistics Pocketbook Summary was published in November 2017 and provides comprehensive economic and trend data on UK food.⁵⁴

⁴⁹ <https://www.food.gov.uk/news-updates/news/2016/15641/fsa-publishes-list-of-incidents-for-july-to-september-2016>

⁵⁰ <https://www.food.gov.uk/news-updates/news/2017/15935/fsa-publishes-list-of-incidents-for-october-to-december-2016>

⁵¹ <https://www.food.gov.uk/news-updates/news/2017/16129/science-report-published-on-use-of-data-science-in-the-fsa>

⁵² Information management in agrifood chains: towards an integrated paperless framework for agrifood trade facilitation

<http://unnex.unescap.org/pub/agriguide15.pdf>

⁵³ <http://unnex.unescap.org>

⁵⁴ <https://www.gov.uk/government/statistics/food-statistics-pocketbook-2017>

1.10 Global data

Two useful compendia of data were published in late 2016: the World Bank ‘Little green data book 2016’⁵⁵ and the United Nations ‘World statistics pocketbook 2016’.⁵⁶ The former is a ready reference on key environmental data for over 200 economies, organised under the headings of agriculture, forestry, biodiversity, energy, emission and pollution, and water and sanitation. The latter presents one-page profiles of 229 countries or areas of the world. The topics covered include: agriculture, balance of payments, education, energy, environment, food, gender, health, industrial production, information and communication, international finance, international tourism, international trade, labour, migration, national accounts, population and prices.

The European Commission published in December 2016 another edition of the common catalogue of varieties of agricultural plant species in accordance with the provisions of Article 17 of Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species. This 35th edition, which runs to over 800 pages, lists all the varieties, the seeds of which, pursuant to Article 16 of the Directive, are not subject to marketing restrictions relating to variety, except in the cases provided for in Article 16(2) and Article 18 of the Directive.⁵⁷

1.11 Machinery of Government

An Order in Council⁵⁸ was made under sections 1 and 2 of the Ministers of the Crown Act 1975 to make provisions in connection with the establishment of the Department for Business, Energy and Industrial Strategy, the Department for Exiting the European Union, (and other departments).

1.12 Food and Agriculture Organisation, FAO

The FAO published in August 2017 a major report on the future of food and agriculture.⁵⁹ The report highlights a number of global trends influencing food security including global population growth, dietary transition to higher consumption of meat, fruits and vegetables, relative to that of cereals, reduced productivity growth, waste, and loss of biodiversity. Hunger and extreme poverty have been reduced globally since the 1990s. Yet, around 700 million people, most of them living in rural areas, are still extremely poor today. In addition, despite undeniable progress in reducing rates of undernourishment and improving levels of nutrition and health, almost 800 million people are chronically hungry and 2 billion suffer micronutrient deficiencies. Conflicts, crises and natural disasters appear to be increasing in number and intensity. These trends pose a series of challenges to food and agriculture that the report elaborates.

The FAO ‘State of Food and Agriculture 2017’ was published in November 2017.⁶⁰ It reiterates the daunting challenge to end hunger and poverty while making agriculture and food systems sustainable. This report presents strategies that can leverage the potential of food systems to become the engine of inclusive economic development and rural prosperity in low-income

⁵⁵ <http://data.worldbank.org/products/data-books/little-green-data-book>

⁵⁶ <http://unstats.un.org/unsd/publications/pocketbook>

⁵⁷ [Common catalogue of varieties of agricultural plant species — 35th complete edition](#)

⁵⁸ The Secretaries of State for Business, Energy and Industrial Strategy, for International Trade and for Exiting the European Union and the Transfer of Functions (Education and Skills) Order 2016 No. 992, http://www.legislation.gov.uk/uksi/2016/992/pdfs/uksi_20160992_en.pdf

⁵⁹ FAO. 2017. The future of food and agriculture – Trends and challenges. Rome, <http://www.fao.org/3/a-i6583e.pdf>

⁶⁰ <http://www.fao.org/publications/sofa/the-state-of-food-and-agriculture/en/>

countries. It analyses the structural and rural transformations now under way, and examines the opportunities and challenges they present to millions of small-scale food producers. It shows how an “agroterritorial” planning approach, focused on connecting cities and towns and their surrounding rural areas, combined with agro-industrial and infrastructure development can generate income opportunities throughout the food sector and underpin sustainable and inclusive rural transformation.

1.13 The Transatlantic Trade and Investment Partnership (TTIP)

In July 2017 the European Parliament published a resolution giving detailed recommendations to the Commission on TTIP.⁶¹

1.14 Control of Mercury

The Control of Mercury (Enforcement) Regulations 2017⁶² were made in December 2017, coming into force on 1 January 2018, except Parts 2 and 3 which come into force on 1 April 2018. The regulations designate competent authorities (The Environment Agency, Northern Ireland Department of Agriculture, Environment and Rural Affairs, the Scottish Environment Protection Agency and the Natural Resources Body for Wales, in their respective jurisdictions) and sets offences and penalties. The regulations provide for the enforcement of Regulation (EU) 2017/852 on Mercury, adopted to fill gaps in existing EU mercury legislation and enable ratification of the Minamata Convention on Mercury. This Convention is designed to protect global human health and the environment from the adverse effects of exposure to mercury and includes restrictions on the import and export of mercury, requirements for the phasing out of the use of mercury in a number of products and processes, as well as measures on interim storage of mercury and its disposal once it becomes waste.

1.15 Plastic microbeads

The prohibition in December 2017 in England of the use of microbeads in rinse-off personal care products was well-publicised. Public Analysts may be called upon to comment on what constitutes a ‘microbead’ thus it is noted that the Environmental Protection (Microbeads) (England) Regulations 2017 defines a ‘microbead’ as any water-insoluble solid plastic particle of less than or equal to 5 mm in any dimension.⁶³

1.16 Metrology

The European Parliament adopted a position at first reading on the European Metrology Programme for Innovation and Research, EMPIR, referenced in the OJ on 22 December 2017,⁶⁴ without further details.

⁶¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.265.01.0035.01.ENG&toc=OJ:C:2017:265:TOC

⁶² <http://www.legislation.gov.uk/uksi/2017/1200/introduction/made>

⁶³ <http://www.legislation.gov.uk/uksi/2017/1312/contents/made>

⁶⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.443.01.0215.01.ENG&toc=OJ:C:2017:443:TOC

2 Food safety

2.1 Food hypersensitivity – (Food Allergy & Food Intolerance)

Background to this topic is to be found in papers published or contributed to from the Government Chemist capability building research on food allergen measurement.⁶⁵⁻⁶⁸

Official risk management of food allergy depends mainly on food labelling. Food ingredients that may trigger food allergy (priority major allergens) or hypersensitivity reactions (gluten and sulfites) are specified in Annex II to Regulation 1169/2011 (the 'Food Information to Consumers Regulation', see Section 3.1 for a fuller discussion of this labelling regulation). If included in a prepacked foodstuff the designated ingredients must be emphasized, for example in **bold print** in the list of ingredients. Disclosure provisions also apply to Annex II foods in prepacked items that are not required to bear a list of ingredients and food sold non-prepacked. The global standard for food allergen labelling is that of the *Codex Alimentarius*.⁶⁹ However, unintended allergens, which might cross contaminate the supply chain during harvest, transport, storage or processing, are treated differently. Food business operators must implement a risk assessment in order to establish whether a hazard is likely to occur, and seek to either eliminate this risk, or reduce the risk of contamination to acceptable levels below which only the most sensitive allergenic subject might react. Advisory ("may contain ...") labelling is often used but should only be applied when there is a demonstrable and significant risk of allergen contamination. Risk assessment approaches have been developed by the Allergen Bureau Voluntary Incidental Trace Allergen Labelling, VITAL® and the Integrated Approaches to Food Allergen and Allergy Management (iFAAM) consortium to manage food allergen risk. These apply milligram per kilogram allergen protein 'action levels' derived from the estimated eliciting dose extrapolated from dose-distribution relationships for the allergen and the food serving size. The eliciting dose is the predicted amount of allergenic food that may provoke an allergic reaction in a given percent of the population.

In December 2017 the Commission published a Notice⁷⁰ dated 13 July 2017 under document number 2017/C 428/01 giving further guidance on Annex II to Regulation 1169/2011. The guidance deals with ways of providing allergen information for pre-packed foods, both when the food bears or does not bear a list of ingredients, labelling of the same allergen derived from several ingredients or processing aids, exemptions when the name of the food clearly refers to the substance or product concerned, voluntary repetition, and updating of Annex II.

The convicted owner of the restaurant which caused the death of Paul Wilson appealed his conviction and sentence. The case was heard before Lord Justice Hickinbottom, Mr Justice Openshaw and His Honour Judge Topolski QC (sitting as a Judge of the Court of Appeal (Criminal Division)) on 12 October 2017. Grounds of appeal were (a) the judge's directions to the jury on a number of issues including on 'breach of duty', 'proof of legal causation', 'standard of care owed by the Appellant to customers', 'standard of proof and vicarious liability', 'foreseeability and risk of death', 'truthfulness of the appellant', and (b) the sentence (six years) was manifestly

⁶⁵ Johnson *et al.* (2014) A multi-laboratory evaluation of a clinically-validated incurred quality control material for analysis of allergens in food, *Food Chem.*, 148: 30-36

⁶⁶ Gowland M. H. and Walker M. J. (2015) Food allergy, a summary of eight cases in the UK criminal and civil courts: effective last resort for vulnerable consumers?, *J. Sci. Food Agric.*, 95: 1979-1990

⁶⁷ Holcombe *et al.* (2015) A peanut quality control material to improve allergen analysis – How difficult can it be?, *Clin. Transl. Allergy*, 5(Suppl 3): P116

⁶⁸ Walker *et al.* (2016) Flawed food allergen analysis—health and supply chain risks and a proposed framework to address urgent analytical needs, *Analyst*, 141: 24-35

⁶⁹ Codex Alimentarius (2010) Codex Alimentarius Commission, General Standard for the Labelling of Prepackaged Foods. CODEX STAN 1-1985 (1985, last amended 2010).

⁷⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.428.01.0001.01.ENG&toc=OJ:C:2017:428:TOC

excessive. All grounds of appeal were carefully considered and rejected. The appeal in respect of both conviction and sentence was dismissed.⁷¹

Following the cumin and mahaleb cases, guidance launched on 7 June 2016 provides food companies that use culinary dried herbs and spices with information on best practice in assessing and protecting the authenticity of these products. The guidance was developed by the British Retail Consortium (BRC), Food and Drink Federation (FDF) and Seasoning and Spice Association (SSA) in liaison with the FSA and FSS.^{72, 73}

Changes to European legislation took effect in mid-2016 which affect gluten-free labelling. Regulation (EC) No 41/2009 provided a legal framework around the term gluten-free and was repealed on 20 July 2016. From this date, rules relating to gluten are provided by Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC), and Commission Implementing Regulation (EU) No 828/2014;⁷⁴ national provisions will allow enforcement at UK level.⁷⁵

Regulation (EU) No 828/2014 stipulates that the statement “*gluten-free*” may only be made where the food as sold to the final consumer contains no more than 20 mg kg⁻¹ of gluten. The statement “*very low gluten*” may only be made where the food, consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been specially processed to reduce the gluten content, contains no more than 100 mg kg⁻¹ of gluten in the food as sold to the final consumer. Additionally, oats contained in a food presented as gluten-free or very low gluten must have been specially produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley, or their crossbred varieties and the gluten content of such oats cannot exceed 20 mg kg⁻¹.

National provisions were made by the Food Information (Scotland) Amendment Regulations 2016, 191,⁷⁶ which came into force on 20 July 2016. These affect SSI 2014/312 which is amended, and SSI 2010/355 which is revoked. These Regulations make provision to enforce in Scotland the requirements of Commission Implementing Regulation (EU) No 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (“Regulation 828/2014”). Regulation 2 makes amendments to the Food Information (Scotland) Regulations 2014 to ensure that Articles 3(1) and 4 of Regulation 828/2014 can be enforced. In particular, they have the effect of making it an offence to fail to comply with those Articles and they ensure that powers of entry are available under section 32 of the Food Safety Act 1990 for the purposes of enforcing those Articles. Regulation 3 revokes the Foodstuffs Suitable for People Intolerant to Gluten (Scotland) Regulations 2010.

Commission Implementing Regulation (EU) No 828/2014 was also implemented:

- In Northern Ireland by the Food Information (Amendment) Regulations (Northern Ireland) 2016.⁷⁷ The Foodstuffs Suitable for People Intolerant to Gluten Regulations (Northern Ireland) 2010 were revoked (note the explanatory note to the 2016 regulations incorrectly cites the latter as 2016 rather than 2010);

⁷¹ Neutral Citation Number: [2017] EWCA Crim 1783, Case No: 201603723 B3, <http://www.bailii.org/ew/cases/EWCA/Crim/2017/1783.html>

⁷² <https://www.fdf.org.uk/news.aspx?article=7539>

⁷³ <https://www.fdf.org.uk/herbs-spices-guidance.aspx>

⁷⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1471529878473&uri=CELEX:32014R0828>

⁷⁵ <https://www.coeliac.org.uk/about-us/news/changes-to-european-legislation-on-gluten-free-labelling/>

⁷⁶ <http://www.legislation.gov.uk/ssi/2016/191/contents/made>

⁷⁷ <https://www.food.gov.uk/sites/default/files/food-information-regulations-ni-2016.pdf>

- In Wales by the Food Information (Wales) (Amendment) Regulations 2016⁷⁸ which revoke the Foodstuffs Suitable for People Intolerant to Gluten (Wales) Regulations 2010.

The fifth FSA Chief Scientific Adviser's report by Professor Guy Poppy focused on food allergy and intolerance, explaining in a readable way the complex and evolving science behind these conditions. The report was launched on 4 November 2016 at a Food Allergy and Food Intolerance Research Programme workshop in London.⁷⁹

The FSA publishes regular reports of surveys into information about the public's self-reported behaviours, attitudes and knowledge relating to food issues. The latest such report, published on 30 March 2017,⁸⁰ (see section 3.7) reported on food allergy and intolerance. Of those who reported an adverse reaction or avoided certain foods, the most common foods that people reported having an adverse reaction to were cows' milk and cows' milk products (22%), cereals containing gluten (13%) and molluscs, e.g. mussels, oysters (11%).

Anaphylaxis to the trigger allergen by a sensitised individual, which is always disturbing and sometimes fatal, requires the rapid parenteral (intramuscular) administration of adrenalin. The Human Medicines (Amendment) Regulations 2017⁸¹ allow auto-injectors containing adrenaline to be administered in schools in an emergency to pupils who are known to require such medication. The regulations apply to England and Northern Ireland.

AOAC INTERNATIONAL (formerly Association of Official Analytical Chemists), published a special edition of its journal, J AOAC International, on food allergens. The edition contained three papers from the Government Chemist. Michael Walker, Malcolm Burns and colleagues described the science behind the ground breaking analysis for allergens by ELISA, molecular biology, and protein mass spectrometry during the investigation of the almond and mahaleb incidents in 2015. Michael and co-authors Hazel Gowland and John Points discussed managing food allergens in the UK retail supply chain in a second paper. Milena Quaglia, Kate Groves and Adam Cryar assessed recovery of food allergens from solid processed matrices applying SI (International System of Units) traceably quantified milk protein solutions and a novel extraction method in a third paper in the special edition. The special edition spanned the globe with contributions from five continents on topics as diverse as food allergen labelling and regulation, quantitative ELISA, targeted and novel mass spectrometry approaches to allergen analysis and analytical devices for use by consumers. The edition is open access and is available on the J AOAC International website.⁸²

2.2 Contaminants

Regulation (EC) No 1881/2006 remains the primary European legislation, the latest consolidated version of which was published in April 2016.⁸³ Domestic implementation is via a set of 'Contaminants in Food' regulations made in each country of the UK in 2013, for example the Contaminants in Food (England) Regulations 2013.⁸⁴ A search of <http://www.legislation.gov.uk/> on the search term 'contaminants' will list the current statutory instruments, their amendments and predecessors. A useful summary of contaminant information is available on the European Commission website.⁸⁵ A guidance document for competent authorities for the control of

⁷⁸ <http://www.legislation.gov.uk/wsi/2016/664/made>

⁷⁹ <https://www.food.gov.uk/news-updates/news/2016/15656/fifth-csa-report-launched>

⁸⁰ <https://www.food.gov.uk/news-updates/news/2017/16111/latest-food-and-you-survey-report-published>

⁸¹ <http://www.legislation.gov.uk/uksi/2017/715/contents/made>

⁸² <http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac/pre-prints;jsessionid=10vwt1ffoh7as.x-ic-live-01>

⁸³ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1466704439817&uri=CELEX:02006R1881-20160401>

⁸⁴ <http://www.legislation.gov.uk/uksi/2013/2196/contents/made>

⁸⁵ http://ec.europa.eu/food/safety/chemical_safety/contaminants/index_en.htm

compliance with EU legislation on aflatoxins is available. Please see below for further details on individual contaminants.⁸⁶

See also section 5.8 on import controls which often feature mycotoxin controls.

The 83rd report of the Joint FAO/WHO Expert Committee on Food Additives was published in June 2017. It includes evaluations of technical, toxicological and/or dietary exposure data for six contaminants or groups of contaminants (aflatoxins, 4,15-diacetoxyscirpenol, (DAS), fumonisins, glycidyl esters, 3-MCPD esters and 3-MCPD, sterigmatocystin) as well as an evaluation of co-exposure of fumonisins with aflatoxins.⁸⁷

2.2.1 Sampling and analysis for contaminants

Commission Regulation (EC) No 333/2007 lays down the methods of sampling and analysis for the official control of levels of certain contaminants in foodstuffs. This was amended by Commission Regulation (EU) 2016/582 of 15 April 2016 as regards the analysis of inorganic arsenic, lead and polycyclic aromatic hydrocarbons and certain performance criteria for analysis. As recorded previously, Regulation (EC) No 1881/2006 was amended by Commission Regulation (EU) 2015/1006 to set maximum levels for inorganic arsenic. In light of this, specific procedures for analysis for inorganic arsenic are required. EN standard 13804 on the determination of elements and their chemical species has been updated. The maximum levels for polycyclic aromatic hydrocarbons (PAH) in cocoa beans and derived products are on a fat basis. Proficiency tests performed by the European Union Reference Laboratory for PAH indicate divergences in the determination of the fat content. It is therefore appropriate to harmonise the approach for the determination of the fat content. These changes are set out in Regulation (EU) 2016/582.⁸⁸

Polychlorinated biphenyls, PCBs, are mentioned in Council Directive 96/23/EC 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products, the annexes of which deal with official sampling. The latest consolidated version is that of 1 July 2013.⁸⁹

2.2.2 Mycotoxins

Previous quarterly reports should be consulted for information, e.g. on ergot, erucic acid and tropane alkaloids, and the impact of mycotoxins in developing countries.

In December 2016 an error was corrected in Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs. The error regarding units seems to have been introduced by Regulation (EU) No 519/2014 of 16 May 2014 in the table in Annex II that prescribed performance criteria for methods for the determination of aflatoxins. Concentrations were stated in mg kg⁻¹ and while it was no doubt generally recognised by practicing analysts that the units should be µg kg⁻¹ in keeping with the limits, a Corrigendum was issued to make this clear.⁹⁰

⁸⁶ https://ec.europa.eu/food/sites/food/files/safety/docs/cs_contaminants_sampling_analysis-guidance-2010_en.pdf

⁸⁷ <http://www.who.int/foodsafety/publications/technical-report-series-1002/en/>

⁸⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.101.01.0003.01.ENG&toc=OJ:L:2016:101:TOC&mc_cid=e1843f434a&mc_eid=f1b5809dbc

⁸⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498122962393&uri=CELEX:01996L0023-20130701>

⁹⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.337.01.0024.01.ENG&toc=OJ:L:2016:337:TOC

2.2.3 Cyanide in raw apricot kernels

An EFSA opinion⁹¹ has confirmed the acute health risks from the presence of cyanogenic glycosides in raw apricot kernels and their derived products owing to amygdalin, the major cyanogenic glycoside present, being degraded to hydrocyanic acid (cyanide) by chewing. Hydrocyanic acid (cyanide) is highly toxic and the acute reference dose would be exceeded by consumption of only a very few unprocessed apricot kernels. Thus Commission Regulation (EU) 2017/1237 of 7 July 2017⁹² amended Regulation (EC) No 1881/2006 to set a maximum level for hydrocyanic acid of 20 µg kg⁻¹ in unprocessed whole, ground, milled, cracked, or chopped apricot kernels placed on the market for the final consumer. The operator who places these products on the market for the final consumer must provide upon request from the competent authority evidence of compliance with the maximum level. Sampling for the control of compliance with the maximum must be performed in accordance with part D.2 of Annex I to Commission Regulation (EC) No 401/2006.

2.2.4 Dioxins and related compounds

Regulation 1881/2006 establishes, with certain derogations, maximum levels for non-dioxin-like polychlorinated biphenyls (PCBs) dioxins and furans and for the sum of dioxins, furans and dioxin-like PCBs in certain foodstuffs. Please refer to previous editions of this review for further details.⁹³

Commission Recommendation 2013/711/EU⁹⁴ sets out action levels for polychlorinated dibenzo-para-dioxins and polychlorinated dibenzofurans (PCDD/Fs) and dioxin-like PCBs in food. The action levels are a tool to be used by competent authorities and food business operators to highlight those cases where it is appropriate to identify a source of contamination and to take the necessary measures in order to reduce or eliminate it.

Commission Regulation (EU) 2017/644 of 5 April 2017⁹⁵ laid down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealed Regulation (EU) No 589/2014. The rationale for additional control of sampling and analysis included ensuring that food business operators applying the controls performed within the framework of Article 4 of Regulation (EC) No 852/2004 (see Section 2.15) apply representative sampling procedures and appropriate laboratory performance criteria. Interestingly, the European Union Reference Laboratory for Dioxins and PCBs has found that analytical results in certain cases are not reliable when appropriate laboratory performance criteria are not applied by laboratories performing the analysis of samples taken by food business operators. Regulation 2017/644 also deletes the use of a decision limit as provided for in Commission Decision 2002/657/EC for the analysis of dioxins and PCBs in food, in favour of an expanded uncertainty using a coverage factor of 2, giving a level confidence of approximately 95 %. The regulation also provides for reporting requirements for physico-chemical methods used for screening in line with the reporting requirements for bioanalytical screening methods and makes other minor amendments.

⁹¹ <https://www.efsa.europa.eu/en/efsajournal/pub/4424>

⁹² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.177.01.0036.01.ENG&toc=OJ:L:2017:177:TOC#ntr3-L_2017177EN.01003601-E0003

⁹³ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/576807/Foodfeedlaw_July-Sept_16_Final.pdf

⁹⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498122697939&uri=CELEX:32013H0711>

⁹⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.092.01.0009.01.ENG&toc=OJ:L:2017:092:TOC

2.3 Non regulated contaminants

There are some contaminants for which legislation is not currently appropriate. Some compounds arise as artefacts of food processing or cooking, examples include:

- Acrylamide
- Glycerol based process contaminants (MCPD and GE)
- Endocrine disruptors
- Nickel

Updates on the above are in previous editions of this review⁹⁶ and further information is recorded below as it arises.

2.3.1 Acrylamide

In 2002 it was discovered that acrylamide, a potential carcinogen, can be formed in food by the reaction of the amino acid asparagine with reducing sugars (particularly glucose and fructose) as part of the Maillard Reaction (a complex series of reactions between amino acids and reducing sugars, usually at increased temperatures). Since then, major international efforts have been mounted to investigate the principal sources of dietary exposure, to assess the associated health risks and develop risk management strategies. In February 2017 FSA carried out an awareness campaign (Go for Gold)⁹⁷ to help people understand how to minimise exposure to acrylamide when cooking at home.

In November 2017 Commission Regulation (EU) 2017/2158⁹⁸ established mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food. Based on EFSA conclusions with respect to the carcinogenic effects of acrylamide and in the absence of any consistent and mandatory measures to be applied by food businesses in order to lower levels of acrylamide, it was considered necessary to reduce the presence of acrylamide in foodstuffs where raw materials contain its precursors by laying down appropriate mitigation measures. The approaches include implementation of good hygiene practice and application of hazard analysis and critical control point (HACCP) principles. Procedures are set out in the Regulation to allow the reduction of the level of exposure to acrylamide and benchmark concentrations have been developed to gauge the effectiveness of mitigation through sampling and analysis which is required of food businesses. Official controls should include sampling and analysis. The benchmark concentrations will be regularly reviewed by the Commission and complementary to this Regulation, the setting of maximum concentrations for acrylamide in certain foods will be considered in accordance with Regulation (EEC) No 315/93 following the entry into force of this Regulation which will apply from 11 April 2018.

The analytical method performance characteristics are laid down in Annex III to the Regulation and include recovery of 75 – 110 %, repeatability (RSD_r), reproducibility (RSD_R), limit of detection (LOD) and limit of quantification (LOQ) criteria. Analysis for acrylamide can be replaced by measurement of product attributes (e.g. colour) or process parameters provided that a statistical correlation can be demonstrated between the product attributes or process parameters and the acrylamide level. If the analytical result, corrected for recovery *but not taking into account the measurement uncertainty*, indicates that a product has exceeded the benchmark level, or contains acrylamide at a level higher than anticipated (taking into account previous analyses, but lower than the benchmark level), then the Food Business Operator (FBO) must carry out a review

⁹⁶ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/576807/Foodfeedlaw_July-Sept_16_Final.pdf

⁹⁷ <https://www.food.gov.uk/news-updates/news/2017/15890/reduce-acrylamide-consumption>

⁹⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.304.01.0024.01.ENG&toc=OJ:L:2017:304:TOC

of the mitigation measures applied and take additional available mitigation measures to ensure that the acrylamide level in the finished product is below the benchmark level. This must be demonstrated by the undertaking of a new representative sampling and analysis, after the introduction of the additional mitigation measures.

The benchmark acrylamide concentrations range from 40 µg kg⁻¹ for certain baby foods, 500 µg kg⁻¹ for ready-to-eat chips (French fries), 750 µg kg⁻¹ for potato crisps, to 850 µg kg⁻¹ for instant (soluble) coffee. Readers should consult the Regulation for details of the mitigation measures, however in brief these include, for example for chips, the use of potato varieties with lower sugar content and storage of potatoes at a temperature higher than 6 °C, washing the potato chips prior to frying, and frying temperatures below 175 °C.

See also the FSA [website section on acrylamide](#) and [FoodDrink Europe toolkits](#). FSA and FSS are working with the British Hospitality Association and other key stakeholders to develop simple guidance which will help the catering and foodservice sectors comply with new rules. Guidelines to aid understanding of the enforcement of the legislation will also be available in 2018.⁹⁹

2.4 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 1333/2008.¹⁰⁰

Regulation (EC) No 1333/2008 is enforced in the UK by the Food Additives, Flavourings, Enzymes and Extraction Solvents (*name of UK country*) Regulations 2013 in each country of the UK.¹⁰¹⁻¹⁰⁴

A database of additives is available on the European Commission website,¹⁰⁵ and entries on specific additives will be retained until captured by the database unless the category is of general interest. Food Additives Legislation Guidance to Compliance (October 2015) is available from FSA.¹⁰⁶

Regulation (EU) No 231/2012¹⁰⁷ sets specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008. A compendium of food additive specifications is available online.¹⁰⁸

The WHO Food Additives Series: 73 prepared by the 82nd meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was published in November 2017 and included safety evaluations of allura red, carob bean gum, pectin, quinoline yellow, rosemary extract, steviol glycosides, tartrazine xanthan gum and certain flavourings.¹⁰⁹

⁹⁹ <https://www.food.gov.uk/news-updates/news/2017/16749/new-eu-acrylamide-legislation>

¹⁰⁰ http://ec.europa.eu/food/food/FAEF/additives/guidance_en.print.htm

¹⁰¹ <http://www.legislation.gov.uk/ukxi/2013/2210/contents/made>

¹⁰² <http://www.legislation.gov.uk/wsi/2013/2591/contents/made>

¹⁰³ <http://www.legislation.gov.uk/ssi/2013/266/contents/made>

¹⁰⁴ <http://www.legislation.gov.uk/nisr/2013/220/contents/made>

¹⁰⁵ http://ec.europa.eu/food/safety/food_improvement_agents/additives/database_en

¹⁰⁶ <https://www.food.gov.uk/sites/default/files/multimedia/pdfs/guidance/food-additives-legislation-guidance-to-compliance.pdf>

¹⁰⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1499108628009&uri=CELEX:02012R0231-20170317>

¹⁰⁸ <http://www.fao.org/3/a-i6413e.pdf>

¹⁰⁹ <http://apps.who.int/iris/bitstream/10665/258934/1/9789241660730-eng.pdf>

2.4.1 Casein and caseinates

The status of food additives in caseinates was clarified by aligning Annex II with the provisions of Directive (EU) 2015/2203¹¹⁰ on caseins and caseinates intended for human consumption. A food category “edible caseinates” was established and the additives authorised in edible caseinates included with the respective conditions of use by Commission Regulation (EU) 2016/691 of 4 May 2016.¹¹¹ Compositional standards for caseinates are given in the Directive, see Section 3.3.1.

2.4.2 Gel forming additives in jelly confectionery

Certain gel forming additives are prohibited in jelly confectionery that conforms with the definition of ‘jelly mini-cups’ given in Part E of Annex II of Regulation 1333/2008. A summary of the background to this, testing products to assess if they conform to the definition of a ‘jelly mini-cup’ and technical appeals to the Government Chemist in this area was published in the September 2017 edition of the IFST house journal FS&T.¹¹²

2.4.3 Potassium carbonate

Commission Regulation (EU) 2017/1270 of 14 July 2017¹¹³ amended Annex II to Regulation 1333/2008 to allow the use of potassium carbonate (E 501) on peeled, cut and shredded fruit and vegetables at *quantum satis* levels. The salt is permitted only in prepacked refrigerated unprocessed fruit and vegetables ready for consumption and prepacked unprocessed and peeled potatoes. During preparation of fresh cut fruit and vegetables, enzymatic activities may lead to a loss in quality of the products, such as browning and structural losses, and to food waste. In order to avoid browning, ascorbic acid (E 300) can be used. However, ascorbic acid tends to break down cell tissue, leading to softening and discoloration of fruit and vegetables after a few days. The use of potassium carbonate (E 501) allows for a more efficient protection against browning as it functions as a stabilizer and acidity regulator and minimizes the damage to tissue caused by ascorbic acid.

2.4.4 Propellants in colour preparations

Commission Regulation (EU) 2017/874 of 22 May 2017 amended Annex III to Regulation 1333/2008 to permit the use of butane (E 943a), isobutane (E 943b) and propane (E 944) in sprays in order to obtain an appropriate homogenous coverage of colours on foods.¹¹⁴

2.4.5 Sulphites

In April 2014 EFSA published a major review of the widely used additives sulphur dioxide and the sulphites group, which are included as a legislated allergen group in the Food Information Regulation 1169/2011 owing to possible intolerance reactions and recorded probable fatalities in consumers sensitive to sulphites in food. EFSA also noted that endogenous sulphites can be generated as a consequence of the body's normal processing of sulphur-containing amino acids and that sulphites may occur as a consequence of fermentation and are naturally present in a

¹¹⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1466676596182&uri=CELEX:32015L2203>

¹¹¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.120.01.0004.01.ENG&toc=OJ:L:2016:120:TOC

¹¹² <https://www.fstjournal.org/features/31-3/choking-hazards>

¹¹³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.184.01.0001.01.ENG&toc=OJ:L:2017:184:TOC

¹¹⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.134.01.0018.01.ENG&toc=OJ:L:2017:134:TOC

number of foods and beverages. EFSA confirmed that although the toxicological database was limited, the current group ADI of 0.7 mg SO₂ equivalent/kg bw per day (derived using a default uncertainty factor of 100) would remain adequate but should be considered temporary whilst the database was improved. The EFSA Panel further concluded that exposure estimates to sulphur dioxide–sulphites were higher than the group ADI for all population groups.¹¹⁵

2.4.6 Additives in wine

Wine making is controlled by Commission Regulation (EC) No 606/2009 which lays down authorised oenological practices (Annex I A). The International Organisation of Vine and Wine (OIV) discuss and adopt oenological practices which may be subsequently incorporated in EU law. For examples please see the previous edition of this report.¹¹⁶

Commission Regulation (EU) 2017/1399 of 28 July 2017¹¹⁷ amended Annex II to Regulation 1333/2008 to permit potassium polyaspartate, E456. Potassium polyaspartate acts as a stabiliser against tartrate crystal precipitation in wine (red, rosé and white wine). It enhances the keeping quality and stability of wine and its use does not have an impact on the sensory properties. The proposed use in wine is at a maximum of 300 mg L⁻¹ with typical levels in the range of 100-200 mg L⁻¹.

Commission Delegated Regulation (EU) 2017/1961 of 2 August 2017 amended Regulation (EC) No 606/2009 to permit the use of filter plates containing zeolites γ -faujasite to adsorb haloanisoles and the treatment of wine with potassium polyaspartate.¹¹⁸

2.4.7 Additives in additives

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. Commission Regulation (EU) 2017/1271 of 14 July 2017¹¹⁹ amended Annex III to permit the use of silicon dioxide (E 551) as an anticaking agent in potassium nitrate (E 252) up to 10,000 mg kg⁻¹.

2.4.8 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 2008.¹²⁰ The regulation is regularly updated, readers should refer to Eur Lex for the latest version as significant amendments are mentioned here on a quarterly basis but only major updates are retained.

In July 2017 Commission Regulation (EU) 2017/1250 amended Annex I to Regulation 1334/2008 to remove from the EU permitted list the flavouring substance 4,5-epoxydec-2(trans)-enal following an EFSA opinion which raised a safety concern with respect to genotoxicity.¹²¹

¹¹⁵ http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4438.pdf

¹¹⁶ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/576807/Foodfeedlaw_July-Sept_16_Final.pdf

¹¹⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.199.01.0008.01.ENG&toc=OJ:L:2017:199:TOC

¹¹⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.279.01.0025.01.ENG&toc=OJ:L:2017:279:TOC

¹¹⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.184.01.0003.01.ENG&toc=OJ:L:2017:184:TOC

¹²⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1445980490072&uri=CELEX:02008R1334-20150729>

¹²¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.179.01.0003.01.ENG&toc=OJ:L:2017:179:TOC

2.5 Endocrine disrupting compounds

There is growing interest in the possible health threat posed by endocrine-disrupting chemicals in the environment, food, and consumer products. Endocrine-disrupting compounds interfere with hormone biosynthesis, metabolism, or action resulting in a deviation from normal homeostatic control or reproduction and may have effects on male and female reproduction, breast development and cancer, prostate cancer, neuroendocrinology, thyroid, metabolism and obesity, and cardiovascular endocrinology. The group of molecules identified as potential endocrine disruptors is highly heterogeneous, structurally diverse and includes polychlorinated biphenyls (PCBs), polybrominated biphenyls (PBBs), dioxins, bisphenol A (BPA), phthalates, some pesticides, and pharmaceutical agents such as diethylstilbestrol (DES). Natural chemicals found in human and animal food (e.g., phytoestrogens, including genistein and coumestrol) can also act as endocrine disruptors although with lower binding affinity to receptors than the above compounds.¹²²

Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017¹²³ set out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council. The full definition is set out in an Annex. A substance shall be considered as having endocrine-disrupting properties with respect to humans or non-target organisms, where it meets the criteria set out in section A or section B of the Annex. With regard to humans a substance shall be considered as having endocrine-disrupting properties if it shows a defined adverse effect in an intact organism or its progeny, has an endocrine mode of action and the adverse effect is a consequence this as assessed by defined scientific evaluation. With respect to non-target organisms the criteria are similar.

Substances with an intended biocidal mode of action, within the meaning of point 6.5, Title 1 of Annex II of Regulation (EU) No 528/2012, to control target organisms other than vertebrates via their endocrine system, present a mode of action which is not expected to be relevant for vertebrates. These substances consequently do not generally pose a risk via this intended mode of action to humans and vertebrates in the environment and are particularly effective and useful in integrated pest management. Thus if the intended biocidal mode of action of the active substance being assessed consists of controlling target organisms other than vertebrates via their endocrine systems, the effects on organisms of the same taxonomic phylum as the targeted one shall not be considered for the identification of the substance as having endocrine-disrupting properties with respect to non-target organisms.

2.6 Extraction solvents

Directive 2009/32/EC applies to extraction solvents used or intended for use in the production of foodstuffs or food ingredients, other than extraction solvents used in the production of food additives, vitamins and other nutritional additives, unless listed in its Annex I.

2.7 Food contact materials

Regulation (EC) No 1935/2004¹²⁴ of the European Parliament and of the Council of 27 October 2004 provides the framework law on materials and articles intended to come into contact with food, implemented in England by the Materials and Articles in Contact with Food

¹²² Diamanti-Kandarakis E., Bourguignon J. P., Giudice L. C., Hauser R., Prins G. S., Soto A. M., Zoeller R. T. and Gore A. C. (2009) Endocrine-disrupting chemicals: an Endocrine Society scientific statement, *Endocrine reviews*, 30(4): 293-342

¹²³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.301.01.0001.01.ENG&toc=OJ:L:2017:301:TOC

¹²⁴ See EUR-Lex for up to date versions of legislation: <http://eur-lex.europa.eu/homepage.html>

(England) Regulations 2012 with equivalents in Scotland, Wales and Northern Ireland. The national regulations implement the requirements of EU Directives (which are not directly applicable) relating to ceramic articles (84/500/EC) and regenerated cellulose film (2007/42/EC). They additionally maintain the controls on vinyl chloride polymer/co-polymer in Directive 78/142/EEC that are not covered under the Food Contact Plastics Regulation.¹²⁵

More detailed provisions are as follows:

- Regulation 2023/2006 on Good Manufacturing Practice
- Regulation 450/2009 on 'Active and Intelligent' Materials and Articles
- Regulation 10/2011 (The 'Food Contact Plastics' Regulation)
- Regulation 1895/2005 on the use of certain epoxy derivatives

The above legislation is best accessed via EUR-Lex although useful advice and links are available on the Commission websites, including a link to database on Food Contact Materials.^{126, 127}

Regulation 10/2009 has been extensively amended by Commission Regulation (EU) 2016/1416¹²⁸ and Commission Regulation (EU) 2017/752 of 28 April 2017¹²⁹ Relevant EFSA opinions were incorporated and textual errors corrected, the definition 'hot-fill' was clarified, and other technical clarifications made including new specific migration limits. In addition in Annex III Table 3, "Food simulants for tests to demonstrate compliance with the overall migration limit", was updated. In Annex IV, point 8(iii) was replaced by '(iii) the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information'.

Commission Regulation 2015/1906¹³⁰ has 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.

In August 2017 the Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2017¹³¹ amended the Materials and Articles in Contact with Food Regulations (Northern Ireland) 2012 to provide for the continued enforcement of Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food) as amended by Commission Regulation (EU) No. 2016/1416. Those amendments include removal of certain offences so as to enable improvement notices to be served to require the same compliance. The failure to comply with an improvement notice becomes an offence under Article 9(2) of the Food Safety (Northern Ireland) Order 1991 (regulation 12 and 14). Examples include, in the 2012 regulations, regulations 7(2) (obligation under Art. 13 of Regulation 450/2009 on supporting documentation), 14(2) (making available certain compositional details to competent authorities), 16(4) (prohibition of use of BFDGE,¹³² NOGE¹³³ and contravention of the specific migration limit

¹²⁵ See the FSA website for general comments and links to national legislation across the UK: <http://www.food.gov.uk/business-industry/manufacturers/contaminants-fcm-guidance/about-the-regulations>

¹²⁶ http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation/index_en.htm

¹²⁷ http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/index_en.htm

¹²⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1416>

¹²⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.113.01.0018.01.ENG&toc=OJ:L:2017:113:TOC

¹³⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.278.01.0011.01.ENG

¹³¹ <http://www.legislation.gov.uk/nisr/2017/157/contents/made>

¹³² BFDGE, bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers, or Bisphenol-F DiGlycidyl Ether

¹³³ NOGE, novolac glycidyl ethers.

for BADGE¹³⁴ and certain derivatives) and others. Consequential administrative amendments are also made.

In Wales the equivalent Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017, Rheoliadau Deunyddiau ac Eitemau mewn Cysylltiad â Bwyd (Cymru) (Diwygio) 2017 were made.¹³⁵

2.7.1 Mineral oil hydrocarbons (MOH)

Mineral oil hydrocarbons (MOH) are derived mainly from crude oil, but also produced synthetically from coal, natural gas and biomass. MOH can be present in food through environmental contamination, lubricants for machinery used during harvesting and food production, processing aids, food additives and food contact materials. Food grade MOH products are treated to minimise the mineral oil aromatic hydrocarbons (MOAH) content.

In 2012 the Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) of EFSA concluded (1) that the potential human health impact of groups of substances among the MOH vary widely. MOAH may act as genotoxic carcinogens, while some mineral oil saturated hydrocarbons (MOSH) can accumulate in human tissue and may cause adverse effects in the liver.

As some MOAH are considered mutagenic and carcinogenic, it is important to organise monitoring of MOH better to understand the relative presence of MOSH and MOAH in food commodities that are major contributors to dietary exposure. Migration from food contact materials such as paper and board packaging is suspected to contribute significantly to the total exposure, hence monitoring should include pre-packaged food, the packaging material and the presence of functional barriers, and equipment used for storage and processing. Certain parameters may increase the migration of MOH from packaging into food, such as storage time and storage conditions. As MOH are easier to detect in high quantities, the sampling strategy should take account of such parameters when their migration is highest.

Commission Recommendation (EU) 2017/84 of 16 January 2017¹³⁶ advised on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food. Member States should, with the active involvement of food business operators as well as manufacturers, processors and distributors of food contact materials and other interested parties, monitor the presence of MOH in food during 2017 and 2018. The monitoring should cover animal fat, bread and rolls, fine bakery ware, breakfast cereals, confectionery (including chocolate) and cocoa, fish meat, fish products (canned fish), grains for human consumption, ices and desserts, oilseeds, pasta, products derived from cereals, pulses, sausages, tree nuts, vegetable oils, as well as food contact materials used for those products. Sampling should be in accordance with the provisions laid down in Commission Regulation (EC) No 333/2007. The European Union Reference Laboratory (EU-RL) for Food Contact Materials is mandated to develop guidance on methods of sampling and analysis.

¹³⁴ BADGE, 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether or Bisphenol-A DiGlycidyl Ether

¹³⁵ <http://www.legislation.gov.uk/wsi/2017/832/contents/made>

¹³⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.012.01.0095.01.ENG&toc=OJ:L:2017:012:TOC

2.8 Marine biotoxins

The overarching law is Regulation (EC) No 853/2004¹³⁷ laying down specific hygiene rules for food of animal origin, which *inter alia* defines ‘marine biotoxins’ as poisonous substances accumulated by bivalve molluscs, in particular as a result of feeding on plankton containing toxins. Limits are prescribed measured in the whole body or any part edible separately):

- (a) for paralytic shellfish poison (PSP), 800 micrograms per kilogram;
- (b) for amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram;
- (c) for okadaic acid, dinophysistoxins and pectenotoxins together, 160 micrograms of okadaic acid equivalents per kilogram;
- (d) for yessotoxins, 3.75 milligrams of yessotoxin equivalent per kilogram; and
- (e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

Regulation 853/2004 is given effect in Scotland by the Food Hygiene (Scotland) Regulations 2006¹³⁸ last amended in 2016. In England the Food Safety and Hygiene (England) Regulations 2013 apply.¹³⁹ Recognised testing methods for marine biotoxins are described in Annex III of Commission Regulation (EC) No 2074/2005 of 5 December 2005.¹⁴⁰ Further information is available from FSA¹⁴¹ on shellfish monitoring and fish and shellfish¹⁴² and from FSS.¹⁴³ EFSA have published a number of opinions on marine biotoxins and further information is also available from the Centre for Environment, Fisheries and Aquaculture Science (Cefas)¹⁴⁴ and the Agri-Food & Biosciences Institute (AFBI).¹⁴⁵

Commission Regulation (EU) 2017/1980 of 31 October 2017¹⁴⁶ amended Annex III to Regulation (EC) No 2074/2005 on the detection method for paralytic shellfish poison (PSP). The PSP content of edible parts of molluscs (the whole body or any part edible separately) must be detected in accordance with the biological testing method or any other internationally recognised method. However if the results are challenged, the reference method shall be the so-called Lawrence method as published in AOAC Official Method 2005.06 (pre-column oxidation liquid chromatography with fluorescence detection, see for example¹⁴⁷).

Commission Implementing Regulation (EU) 2017/2369 of 18 December 2017 extended to 31 December 2021 the provisions of Implementing Regulation (EU) No 743/2013 introducing protective measures on imports of bivalve molluscs from Turkey intended for human consumption. The measures include a ban on importation of live and chilled bivalve molluscs, and testing for *Escherichia coli* and marine biotoxins in all consignments of frozen bivalve molluscs. The extension arose from deficiencies in the official control system, notably in the performance of laboratories.¹⁴⁸

¹³⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1494593945343&uri=CELEX:02004R0853-20160401>

¹³⁸ <http://www.legislation.gov.uk/ssi/2006/3/regulation/13/made>

¹³⁹ <http://www.legislation.gov.uk/ukxi/2013/2996/contents/made>

¹⁴⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1494594527755&uri=CELEX:02005R2074-20160603>

¹⁴¹ <https://www.food.gov.uk/enforcement/monitoring/shellfish/>

¹⁴² <https://www.food.gov.uk/business-industry/fish-shellfish>

¹⁴³ <http://www.foodstandards.gov.scot/food-safety-standards/advice-business-and-industry/shellfish>

¹⁴⁴ <https://www.cefas.co.uk/>

¹⁴⁵ <https://www.afbini.gov.uk/articles/marine-biotoxins-shellfish>

¹⁴⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.285.01.0008.01.ENG&toc=OJ:L:2017:285:TOC

¹⁴⁷ <https://www.food.gov.uk/science/research/foodborneillness/p01programme/p01prolist/fs235002a>

¹⁴⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.337.01.0026.01.ENG&toc=OJ:L:2017:337:TOC

2.9 Pesticides

Guidance on maximum residue levels (MRLs) for pesticides and analytical methods is given on the Commission website.¹⁴⁹ Commission Implementing Regulation (EU) 2017/660 of 6 April 2017 extended previous coordinated multiannual control programme to ensure compliance with MRLs and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin to 2018, 2019 and 2020 with amended provisions.¹⁵⁰

Regulation (EC) No 396/2005 governs MRLs of pesticides in or on food and feed of plant and animal origin; Annexes II, III and V to the regulation are regularly amended as regards MRLs and can be seen on the EU Pesticides Database.^{151, 152}

Individual records of MRLs and changes thereto are not reproduced here.

Rules for the authorisation of pesticides (plant protection products) in commercial form and for their placing on the market, use and control within the European Union are contained in Regulation (EC) No 1107/2009 of the European Parliament and of the Council.¹⁵³ Regulation 1107/2009 is implemented by Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011¹⁵⁴ which is frequently updated.

Commission Regulation (EU) 2017/1432 of 7 August 2017¹⁵⁵ amended Regulation 1107/2009 on criteria for the approval of low-risk active substances which the latter aims at facilitating placing on the market by setting criteria for their identification and accelerating the approval procedure. However there are in the Regulation 14 classes of substances, such as carcinogens or skin sensitisers, which cannot be considered low risk. Regulation 2017/1432 adds as low-risk substances semio-chemicals, which are substances emitted by plants, animals and other organisms which are used for intra- and inter-species communication, have a target-specific and non-toxic mode of action and are naturally occurring. They are generally effective at very low rates, often comparable to levels that occur naturally. Certain micro-organisms may also be considered to be of low-risk unless at strain level multiple resistance to antimicrobials used in human or veterinary medicine has been demonstrated. Certain baculoviruses may also be considered low risk unless, at strain level, adverse effects on non-target insects has been demonstrated.

2.9.1 Biocidal Products

The Biocidal Product Regulation (Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product. The regulation is frequently updated. Further information is available on the website of the European Chemicals Agency.¹⁵⁶

¹⁴⁹ http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

¹⁵⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.094.01.0012.01.ENG&toc=OJ:L:2017:094:TOC

¹⁵¹ <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>

¹⁵² http://ec.europa.eu/food/plant/pesticides/max_residue_levels/index_en.htm

¹⁵³ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474202948544&uri=CELEX:02009R1107-20140630> (but see EUR-Lex for latest version)

¹⁵⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474199567547&uri=CELEX:32011R0540> (but see EUR-Lex for latest version)

¹⁵⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.205.01.0059.01.ENG&toc=OJ:L:2017:205:TOC

¹⁵⁶ <https://echa.europa.eu/regulations/biocidal-products-regulation>

Commission Delegated Regulation (EU) 2017/698 of 3 February 2017 amended Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012.¹⁵⁷

2.10 Products of animal origin

Regulations (EC) 853/2004 and 854/2004 control the import of products of animal origin. These are to be imported only from a third country or a part of third country that appears on a designated list.

Commission Regulation (EU) 2017/1978 of 31 October 2017 amended Annex III to Regulation (EC) No 853/2004 as regard echinoderms (e.g. sea cucumbers) harvested outside classified production areas, supplemented by Commission Regulation (EU) 2017/1979 of 31 October 2017 with amended Annex II to Regulation (EC) No 854/2004 with specific rules on such echinoderms.

Commission Regulation (EU) 2017/1981 of 31 October 2017 amended Annex III to Regulation (EC) No 853/2004 as regards temperature conditions during transport of meat.

2.11 Radioactivity

Commission Implementing Regulation (EU) 2016/6 of 5 January 2016 relaxed the 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 repealed Implementing Regulation (EU) No 322/2014.

Commission Implementing Regulation (EU) 2017/2058 of 10 November 2017 further relaxed Regulation (EU) 2016/6 on foot of data gathered by the Japanese authorities and import controls at the EU border.¹⁵⁸

Council Regulation (Euratom) 2016/52¹⁵⁹ sets out maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency, and repeals Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90.

See also (for example) Welsh private water supply regulations covering monitoring of radioactivity in water (see Section 2.16).

2.12 Transmissible spongiform encephalopathies

Transmissible Spongiform Encephalopathies, TSE, are a family of diseases occurring in man and animals and are characterised by a degeneration of brain tissue to a sponge-like appearance leading to death. The family includes diseases such as Creutzfeldt-Jakob Disease, CJD, variant Creutzfeldt-Jakob Disease, vCJD and Kuru in humans, Bovine Spongiform Encephalopathy, BSE, in cattle, Scrapie in small ruminants (sheep and goats), Chronic Wasting Disease in cervids (e.g. deer) and Transmissible Mink Encephalopathy. The commonly accepted cause of the TSE

¹⁵⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.103.01.0001.01.ENG&toc=OJ:L:2017:103:TOC

¹⁵⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.294.01.0029.01.ENG&toc=OJ:L:2017:294:TOC

¹⁵⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.013.01.0002.01.ENG&toc=OJ:L:2016:013:TOC

diseases is a transmissible agent called a prion (PrPres), which is an abnormal form of a protein. The framework legislation is Regulation (EC) No 999/2001.¹⁶⁰

Commission Regulation (EU) 2016/1396 of 18 August 2016 amended certain Annexes to Regulation (No 999/2001. For example for the purposes of official BSE risk status recognition, “atypical BSE” – a condition believed to occur spontaneously in all cattle populations at a very low rate – was excluded. Legislative references were updated and technical labelling requirements around removal of vertebral column from carcasses were amended. Further technical amendments were made for which the reader is advised to consult Regulation 2016/1396.¹⁶¹

Commission Implementing Decision (EU) 2016/2002 of 8 November 2016 amended Annex E to Council Directive 91/68/EEC, Annex III to Commission Decision 2010/470/EU and Annex II to Commission Decision 2010/472/EU concerning trade in and imports into the EU of ovine and caprine animals, and semen of animals of the ovine and caprine species in relation to the rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.¹⁶²

Commission Regulation (EU) 2017/110 of 23 January 2017 amended Annexes IV and X to Regulation (EC) No 999/2001 that *inter alia*, prohibit the feeding to ruminants of protein derived from animals, except feeding to unweaned ruminants of milk replacers containing fishmeal which are produced, placed on the market and used in accordance with the specific conditions. Regulation 2017/110 allows the possibility of using starfish or farmed aquatic invertebrates, other than molluscs and crustaceans, for the production of fishmeal for unweaned ruminants.¹⁶³

Commission Regulation (EU) 2017/893 of 24 May 2017 amended Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein.¹⁶⁴ Processed animal protein derived from insects and compound feed containing such processed animal protein is authorised for feeding aquaculture animals and other amendments are made.

Commission Regulation (EU) 2017/894 of 24 May 2017 amended Annexes III and VII to Regulation (EC) No 999/2001 as regards the genotyping of ovine animals.¹⁶⁵

Commission Implementing Decision (EU) 2017/1396 of 26 July 2017 amended the Annex to Decision 2007/453/EC as regards country BSE status. Northern Ireland, Scotland and Poland were recognised as having a negligible BSE risk. England and Wales remain currently listed as countries with a controlled BSE risk.¹⁶⁶

2.13 Toxicology

EFSA have established ‘OpenFoodTox’, a new database that provides access to information from over 1,650 EFSA scientific outputs about the toxicity of chemicals found in the food and feed

¹⁶⁰ http://ec.europa.eu/food/safety/biosafety/food_borne_diseases/tse_bse/index_en.htm

¹⁶¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1396>

¹⁶² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.308.01.0029.01.ENG&toc=OJ:L:2016:308:TOC

¹⁶³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.018.01.0042.01.ENG&toc=OJ:L:2017:018:TOC

¹⁶⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.138.01.0092.01.ENG&toc=OJ:L:2017:138:TOC

¹⁶⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.138.01.0117.01.ENG&toc=OJ:L:2017:138:TOC

¹⁶⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.197.01.0009.01.ENG&toc=OJ:L:2017:197:TOC

chain. An editorial published in the EFSA Journal in January 2017 describes how to use the database.¹⁶⁷

2.14 Veterinary residues

Commission Regulation (EU) No 37/2010 of 22 December 2009 deals with MRLs of veterinary medicinal products in foodstuffs of animal origin. Domestic effect is given by the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015¹⁶⁸ and, in Northern Ireland, by the Animal and Animal Products (Examination for Residues and Maximum Residue Limits) (Northern Ireland) 2016 (SR 54).¹⁶⁹

Regulation (EU) No 37/2010 is regularly amended as regards MRLs. Further information is available from the European Medicines Agency (EMA)¹⁷⁰ and on the European Commission website.¹⁷¹ The latest consolidated version of Regulation 37/2010 (available on EUR-Lex) should be consulted for MRLs however there is a time-lag between amendments being made and their incorporation into the consolidated version. It is therefore best to search EUR-Lex from the date of the last amendment to ensure full coverage.

Toxicological evaluation of veterinary residues is carried out by the Joint FAO/WHO Expert Committee on Food Additives, JECFA, an international expert scientific committee administered jointly by the FAO and the WHO.¹⁷²

Commission Implementing Decision (EU) 2016/1774 of 4 October 2016 amended Decision 2010/381/EU which requires at least 10 % of consignments of aquaculture products from India for human consumption to be tested for the presence of pharmacologically active substances, in particular, chloramphenicol, tetracycline, oxytetracycline and chlortetracycline and of metabolites of nitrofurans. Decision (EU) 2016/1774 strengthened surveillance by requiring 50% of consignments to be tested but relieved Member States of the obligation for quarterly reporting in light of the implementation of the integrated computerised veterinary system ('Traces') in accordance with Article 3 of Commission Decision 2004/292/EC.¹⁷³

Commission Implementing Regulation (EU) 2017/12 of 6 January 2017 established a standard format for applications and requests to the European Medicines Agency (EMA) for the establishment of maximum residue limits in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council. The format includes the list of information that should accompany such applications, which includes a proposed method of analysis (including limit of quantification and reference, where relevant).¹⁷⁴

Official sampling strategy, sampling levels and frequency are set out in Annexes III and IV to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products, (latest consolidated version 1 July 2013¹⁷⁵). Commission Decision 98/179/EC of 23 February 1998 (latest consolidated version 1 July 2013¹⁷⁶)

¹⁶⁷ <http://www.efsa.europa.eu/en/press/news/170118-0>

¹⁶⁸ http://www.legislation.gov.uk/ukxi/2015/787/pdfs/ukxi_20150787_en.pdf

¹⁶⁹ http://www.legislation.gov.uk/nisr/2016/54/pdfs/nisr_20160054_en.pdf

¹⁷⁰ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000165.jsp

¹⁷¹ http://ec.europa.eu/health/documents/community-register/index_en.htm

¹⁷² <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/>

¹⁷³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.271.01.0007.01.ENG&toc=OJ:L:2016:271:TOC

¹⁷⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.004.01.0001.01.ENG&toc=OJ:L:2017:004:TOC

¹⁷⁵ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498122962393&uri=CELEX:01996L0023-20130701>

¹⁷⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498134918739&uri=CELEX:01998D0179-20130701>

lays down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products and includes provision, unless technically impossible or not required by national legislation, to divide each sample into at least two equivalent sub-samples each allowing the complete analytical procedure. The subdivision can take place at the sampling location or in the laboratory.

Commission Regulation (EU) 2017/880 of 23 May 2017 set out rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff, for another foodstuff derived from the same species and a maximum residue limit established for a pharmacologically active substance in one or more species for application to other species, in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council.¹⁷⁷

A summary of why and how veterinary residues are controlled in food and current problems arising from technical appeals to the Government Chemist in this area was published in the June edition of the IFST house journal FS&T.¹⁷⁸

2.15 Food Hygiene

Good food hygiene means controlling harmful micro-organisms which can cause serious illness. The four essential measures are (a) to control cross-contamination, (b) effective cleaning (c) thorough cooking and (d) immediate chilling after cooking. These are summarised as ‘cook, chill, clean, separate’.¹⁷⁹ HACCP (Hazard Analysis and Critical Control Point) is a key system that helps food business operators address food hygiene.¹⁸⁰ Food Hygiene is controlled legislatively by Food Safety and Hygiene Regulations, currently the Food Safety and Hygiene (England) Regulations 2013¹⁸¹ with equivalents in Wales,¹⁸² Scotland¹⁸³ and Northern Ireland.¹⁸⁴ These regulations identify the “EU Hygiene Regulations” as Regulation 852/2004, Regulation 853/2004, Regulation 854/2004, Regulation 2073/2005 and Regulation 2075/2005. A schedule to the UK regulations lists the means of the following hygiene measures: Decision 2006/766, Directive 2004/41, Regulation 178/2002, Regulation 852/2004, Regulation 853/2004, Regulation 854/2004, “Regulation 882/2004”, “Regulation 1688/2005”, “Regulation 2073/2005”, “Regulation 2074/2005”, Regulation 2075/2005, Regulation 1020/2008, Regulation 1021/2008, Regulation 596/2009, Regulation 669/2009, Regulation 1169/2011, Regulation 28/2012 and Regulation 1079/2013.

EU Regulation No. 2073/2005 on microbiological criteria for foods (as amended by EU Regulation No. 1441/2007) complements the food hygiene legislation and applies to all food businesses involved in the production and handling of food.¹⁸⁵ Guidance on microbiological criteria is available from Public Health England¹⁸⁶ and from IFST on aspects such as Shigatoxin-producing *E. coli*, fresh produce safety, foodborne viral infections, campylobacter, cyclospora, and cryptosporidium.¹⁸⁷

¹⁷⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.135.01.0001.01.ENG&toc=OJ:L:2017:135:TOC

¹⁷⁸ Walker M. and Gray L. (2017), Veterinary residues in food, FS&T, 31, 23-27 <http://fstjournal.org/features/31-2/veterinary-residues>

¹⁷⁹ <https://www.food.gov.uk/business-industry/food-hygiene>

¹⁸⁰ <https://www.food.gov.uk/business-industry/food-hygiene/haccp>

¹⁸¹ <http://www.legislation.gov.uk/ukxi/2013/2996/note/made>

¹⁸² Food Hygiene (Wales) Regulations 2006 with many subsequent amendments

¹⁸³ Food Hygiene (Scotland) Regulations 2006 with many subsequent amendments

¹⁸⁴ The Food Hygiene Regulations (Northern Ireland) 2006 with many subsequent amendments

¹⁸⁵ <https://www.food.gov.uk/business-industry/guidancenotes/hygguid/microbiolreg>

¹⁸⁶ PHE, 2009, Ready-to-eat foods: microbiological safety assessment guidelines

¹⁸⁶ <https://www.gov.uk/government/publications/ready-to-eat-foods-microbiological-safety-assessment-guidelines>

¹⁸⁷ <http://www.ifst.org/knowledge-centre/information-statements>

Commission Regulation (EU) 2017/1495 of 23 August 2017¹⁸⁸ amended Regulation (EC) No 2073/2005 as regards *Campylobacter* in broiler carcasses.

Regulation (EC) No 852/2004 of 29 April 2004¹⁸⁹ on the hygiene of foodstuffs imposes responsibilities and duties on food business operators including HACCP, temperature control, maintenance of a cold chain and sampling and analysis.

Food Hygiene (Amendment) Regulations made in England, Wales, Scotland and Northern Ireland came into force in October 2016 and made various amendments to provide for the execution and enforcement of Commission Implementing Regulation (EU) 2015/1375 laying down specific rules on official controls for *Trichinella* in meat.¹⁹⁰⁻¹⁹³

In March 2017 Health Protection Scotland published an Incident Management Team report on a national outbreak of *Escherichia coli* O157 Phage Type 21/28 in Scotland in July-September 2016.¹⁹⁴ The incident attracted considerable publicity.

The Commission has produced a guidance document addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene (2017/C 163/01).¹⁹⁵

Commission Decision (EU) 2017/1583 of 1 September 2017 specified, pursuant to Directive 2006/7/EC of the European Parliament and of the Council, EN ISO 17994:2014 as the standard on the equivalence of microbiological methods, (notified under document C(2017) 5843). This is in relation to Directive 2006/7/EC on the management of bathing water quality. EN ISO 17994:2014 replaces an outdated standard and introduces technical updates (e.g. terminology, clearer specifications, and addition of a new Annex on technical calculations).¹⁹⁶

On 11 October 2017 the FSA announced a change to its advice about eating eggs – infants, children, pregnant women and elderly people can now safely eat raw or lightly cooked eggs that are produced under the British Lion Code of Practice. The revised advice, based on the scientific evidence assessed by the Advisory Committee on the Microbiological Safety of Food (ACMSF), means that people vulnerable to infection or who are likely to suffer serious symptoms from food poisoning can now safely eat raw or lightly cooked hen eggs or foods containing them.¹⁹⁷

The World Health Organization has published guidance on the selection and application of methods for the detection and enumeration of human-pathogenic halophilic vibrio spp. in seafood. This considers the range of potential methods from culture based to molecular biological, and proposes the use of performance characteristics to select the most appropriate method according to the potential end use of the data generated, for example, harvest area monitoring, post-harvest process verification, end product monitoring, and outbreak investigation.

¹⁸⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.218.01.0001.01.ENG&toc=OJ:L:2017:218:TOC

¹⁸⁹ Latest consolidated version 20.04.2009, <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498136347793&uri=CELEX:02004R0852-20090420>

¹⁹⁰ The Food Safety and Hygiene (England) (Amendment) Regulations 2016 <http://legislation.data.gov.uk/ukxi/2016/868/made/data.pdf>

¹⁹¹ The Food Hygiene (Wales) (Amendment) Regulations 2016, <http://www.legislation.gov.uk/cy/wsi/2016/845/made>

¹⁹² The Food Hygiene (Scotland) Amendment Regulations 2016 http://www.legislation.gov.uk/ssi/2016/260/pdfs/ssi_20160260_en.pdf

¹⁹³ <http://www.legislation.gov.uk/nisr/2016/345/contents/made>

¹⁹⁴ <http://www.hps.scot.nhs.uk/pubs/detail.aspx?id=3200>

¹⁹⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.163.01.0001.01.ENG&toc=OJ:C:2017:163:TOC

¹⁹⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1512389494729&uri=CELEX:32017D1583>

¹⁹⁷ <https://www.food.gov.uk/news-updates/news/2017/16597/new-advice-on-eating-runny-eggs>

Aspects of data requirements that could support national and regional risk assessments are also addressed.¹⁹⁸

Commission Implementing Regulation (EU) 2017/2369 of 18 December 2017 extended to 31 December 2021 the provisions of Implementing Regulation (EU) No 743/2013, introducing protective measures on imports of bivalve molluscs from Turkey intended for human consumption. The measures include a ban on importation of live and chilled bivalve molluscs and testing for *Escherichia coli* and marine biotoxins in all consignments of frozen bivalve molluscs. The extension arose from deficiencies in the official control system, notably in the performance of laboratories.¹⁹⁹

Pursuant to Article 9 of Regulation 852/2004 the Commission has published²⁰⁰ the 'European Guide for Good Hygiene Practices in the production of artisanal cheese and dairy products',²⁰¹ authored by the Farmhouse and Artisan Cheese & Dairy Producers European Network (FACE network). This is one of a suite of guidance available on the Commission website.²⁰²

2.15.1 Enterohemorrhagic *Escherichia coli* - seeds and sprouted seeds

The Enterohemorrhagic *Escherichia coli* (EHEC) crisis of 2011 focused mainly in Germany with hemolytic-uremic syndrome (HUS) and bloody diarrhoea infecting almost 4,000 people and resulting in 53 deaths.²⁰³ Following EFSA's opinion²⁰⁴ on the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds new EU legislation was brought in to supplement general food safety requirements in Regulation 178/2002 and hygienic production covered by Regulation 852/2004. These were Commission Implementing Regulation (EU) No 208/2013 on traceability requirements for sprouts and seeds intended for the production of sprouts, Commission Regulation (EU) No 209/2013 (amending Regulation (EC) No 2073/2005) on microbiological criterion for sprouts, Commission Regulation (EU) No 210/2013 on the approval of establishments producing sprouts and Commission Regulation (EU) No 211/2013 (amended by Commission Regulation (EU) No 704/2014) on certification requirements for imports of sprouts and seeds for sprouting into the EU. The requirements of the above regulations and comprehensive instructions on hygienic practices for the safe production of sprouts and seeds for sprouting are included in a guideline produced by the European Sprouted Seeds Association and published by the Commission in the Official Journal in July 2017 under the reference 2017/C 220/03.²⁰⁵

2.15.2 Food hygiene rating schemes

Food Hygiene Rating Schemes help consumers choose where to eat out or shop for food by giving them information about the hygiene standards in restaurants, takeaways and food shops.²⁰⁶

In England, Northern Ireland and Wales the FSA operates the Food Hygiene Rating Scheme while FSS operates the Food Hygiene Information Scheme in Scotland, all hinging on local

¹⁹⁸ http://www.who.int/foodsafety/publications/mra_22/en/

¹⁹⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.337.01.0026.01.ENG&toc=OJ:L:2017:337:TOC

²⁰⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.440.01.0001.01.ENG&toc=OJ:C:2017:440:TOC

²⁰¹ https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_guidance_artisanal-cheese-and-dairy-products_en.pdf

²⁰² https://ec.europa.eu/food/safety/biosafety/food_hygiene/guidance_en

²⁰³ http://www.bfr.bund.de/en/ehec_outbreak_2011-186689.html

²⁰⁴ <http://www.efsa.europa.eu/en/efsajournal/pub/2424>

²⁰⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.220.01.0029.01.ENG&toc=OJ:C:2017:220:TOC

²⁰⁶ <https://www.food.gov.uk/business-industry/hygieneratings>

authority hygiene inspections. The schemes in Wales and Northern Ireland have gained statutory force with the Food Hygiene Rating (Promotion of Food Hygiene Rating) (Wales) Regulations 2016, No. 429 (W. 138)²⁰⁷ which came into force on 28 November 2016 and The Food Hygiene Rating Act (Northern Ireland) 2016.²⁰⁸ In Wales the regulation applies to establishments which supply takeaway food and requires a conspicuous notice in Welsh and English to indicate the availability of the business food hygiene rating. Receipts from fixed penalties can only be used for the purposes of the Public Health (Wales) Act 2017²⁰⁹ and regulations made under it. The Food Hygiene Rating Regulations (Northern Ireland) 2016 no. 313²¹⁰ and the Food Hygiene Rating (Transitional Provisions) Order (Northern Ireland) 2016 no. 314²¹¹ give salient details including exemptions, the form of display of the rating and a fixed penalty notice for failure to display. The Food Hygiene Rating (2016 Act) (Commencement) Order (Northern Ireland) 2016 no. 328 appointed 7 October 2016 for the coming into operation of the Act.²¹² The hygiene rating is displayed on the rating sticker given by the local authority following inspection; in England Wales and Northern Ireland the rating ranges from '5' which means the food hygiene standards are very good, down to '0' where urgent improvement is necessary. In England FSA is exploring how a viable statutory scheme could be delivered in the future in line with the FSA's 'Regulating our Future' programme and in the meantime the current voluntary scheme in England is being aligned with the statutory schemes in Wales and Northern Ireland as far as possible without legislative requirements.

In December 2016 the Food Hygiene Rating (Fee and Fixed Penalty Amount) Order (Northern Ireland) 2016 was made²¹³ coming into force when made and establishing a fee for re-rating an establishment of £150.00 and a fixed penalty of £200.00 if, without reasonable excuse, no valid (or an invalid) food hygiene rating is displayed (or, where appropriate, made available online).

2.16 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 waters²¹⁴ (recast)²¹⁵ 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.²¹⁶

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);

²⁰⁷ http://www.legislation.gov.uk/wsi/2016/429/pdfs/wsi_20160429_mi.pdf

²⁰⁸ Food Hygiene Rating Act (Northern Ireland) 2016, Ch 3 <http://origin-www.legislation.gov.uk/nia/2016/3/enacted>

²⁰⁹ <http://www.legislation.gov.uk/anaw/2017/2/contents/enacted>

²¹⁰ <http://www.legislation.gov.uk/nisr/2016/313/made>

²¹¹ <http://www.legislation.gov.uk/nisr/2016/314/made>

²¹² <http://www.legislation.gov.uk/nisr/2016/328/made/data.pdf>

²¹³ http://www.legislation.gov.uk/nisr/2016/425/pdfs/nisr_20160425_en.pdf

²¹⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1453734625466&uri=CELEX:32009L0054>

²¹⁵ Which repeals and replaces Directive 80/777/EEC.

²¹⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1453734764128&uri=CELEX:32003L0040>

- The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015 No. 1867 (W. 274) (which revoked and replaced the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007);
- The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2015 (SR 2015 No. 365) which revoked and replaced the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2007.

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015^{217, 218} amended 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 2015²¹⁹ (SI 1867, W274) and in Northern Ireland with the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2015²²⁰ (SR 365).

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015 (correction slip) of 25 May 2017 made correction to the Welsh language version of the regulations.²²¹

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2017, made on 6 September 2017 and brought into force on 27 October 2017 again amended the 2007 Regulations as a result of amendments to their European measures. Commission Directive (EU) 2015/1787 amended Annexes II and III to Council Directive 98/83/EC as regards the quality of water intended for human consumption. These Regulations transpose the provisions of the Directive only in respect of bottled drinking water which is marketed as spring water or bottled drinking water. The remaining provisions of the Directive are implemented by the Public Water Supplies (Scotland) Amendment Regulations 2017 and the Water Intended for Human Consumption (Private Supplies) (Scotland) Regulations 2017. The Regulations remove the obligations on food authorities to check monitor and to audit monitor spring water and bottled drinking water in regulation 16 and schedules 9 to 11 of the 2007 Regulations. They thus clarify enforcement provisions, in particular to remove obligations on food authorities to monitor substances such as ammonia and oxidisability in spring water and bottled water that relate more properly to non-bottled water supplies.²²² These regulations have now been amended many times and appear to be a prime candidate for consolidation.

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2017,²²³ made 17 September 2017, and in force on 27 October 2017, amended the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015.

²¹⁷ http://www.legislation.gov.uk/ssi/2015/363/pdfs/ssi_20150363_en.pdf
²¹⁸ http://www.legislation.gov.uk/ssi/2015/363/pdfs/ssics_20150363_en.pdf correction slip
²¹⁹ http://www.legislation.gov.uk/wsi/2015/1867/pdfs/wsi_20151867_mi.pdf
²²⁰ http://www.legislation.gov.uk/nisr/2015/365/pdfs/nisr_20150365_en.pdf
²²¹ http://www.legislation.gov.uk/wsi/2015/1867/pdfs/wsics_20151867_mi.pdf
²²² <http://www.legislation.gov.uk/ssi/2017/287/contents/made>
²²³ <http://www.legislation.gov.uk/wsi/2017/935/contents/made>

They implement the amended monitoring requirements for spring water and bottled drinking water mentioned above in the Scottish 2017 amending Regulations (Welsh regulations 8 and 14). They also allow natural mineral water and spring water that has been subjected to fluoride removal treatment or ozone-enriched air treatment in a non-EEA State to be sold in Wales if the treatments are suitably authorised (regulations 3, 9 and 10). They clarify that natural mineral water and spring water extracted otherwise than in Wales may only be sold in Wales if it complies with the requirements as described in the 2015 Regulations in relation to exploitation (in the case of natural mineral water), treatments and additions, and bottling and labelling requirements (regulations 4 and 7). The rules on treatments and additions do not prevent spring water from being used in the manufacture of soft drinks (regulation 5). The Regulations prohibit the advertising of spring water in a way that is liable to cause the water to be confused with a natural mineral water, and prohibit the use of “mineral water”, “dŵr mwynol”, or its equivalent in any other language, in the advertising of spring water (regulation 6). The exemption period (5 years) from monitoring for certain radiological substances is clarified (regulation 15). Lastly, several errors in previous regulations are corrected.

In October 2017 the Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) Regulations (Northern Ireland) 2017²²⁴ amended the parent 2015 Northern Ireland regulations. In so doing, they implement Commission Directive (EU) 2015/1787 which amends Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption. New definitions of “fluoride removal treatment” and “ozone-enriched air treatment” are given, it is clarified that natural mineral water produced outside of Northern Ireland is required to comply with the relevant requirements of the 2015 Regulations when sold in Northern Ireland and the rules on treatments and additions do not prevent spring water from being used in the manufacture of soft drinks. The advertising of spring water must not cause confusion of the water with a natural mineral water. A person may not sell as spring water, water that has been subject to treatment or addition regardless of where that treatment or addition took place. Similar provisions on checking and audit monitoring for spring water and bottled drinking water as well as certain radiological provisions and corrections as in Scotland and Wales are introduced.

Commission Directive 2015/1787²²⁵ 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.

The Private Water Supplies (Wales) (Amendment) Regulations 2016 No. 411 (W. 129)²²⁶ came into force on 14 April 2016 and amend the Private Water Supplies (Wales) Regulations 2010 to implement Council Directive 2013/51/Euratom on the protection of the health of the general public with regard to radioactive substances in water intended for human consumption from private water supplies. Regulation 3 of these Regulations inserts new regulation 10A (monitoring of radioactive substances: general) into the 2010 Regulations to make provision for new requirements in relation to monitoring for radon, tritium and indicative dose (“the radioactive substances parameters”). Regulation 3 also inserts new regulation 10B (monitoring of radioactive substances: supplies to a single dwelling not used for a commercial or public activity) into the 2010 Regulations. Further monitoring requirements are included in new Schedule 2A. Regulation 5 inserts a new Part (Part 3 – radioactive substances parameters) into Schedule 1 to the 2010 Regulations. The new Part 3 includes Table D which sets parametric values for the radioactive substances parameters. Regulations 2, 4 and 6 of these Regulations make consequential

²²⁴ <http://www.legislation.gov.uk/nisr/2017/201/contents/made>

²²⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.260.01.0006.01.ENG

²²⁶ <http://www.assembly.wales/laid%20documents/sub-ld10651/sub-ld10651-e.pdf>

amendments in light of regulation 6. Regulation 8 of these Regulations inserts a new Part (Part 3 – monitoring for indicative dose and analytical performance characteristics) into Schedule 3 to the 2010 Regulations. The new Part 3 makes provision for additional sampling and analysis requirements in relation to the radioactive substances parameters listed in the new Table D in Part 3 of Schedule 1.

The Water Supply (Water Quality) Regulations 2016, 614,²²⁷ enabling power: Water Industry Act 1991, and European Communities Act 1972 came into force on 27 June 2016. It affects:

- SI 2007/3544
- SI 2016/303 amended and SI 2002/2469
- SI 2005/2035
- SI 2007/3544
- SI 2013/235, SI 2013/1387 partially revoked and SI 2000/3184
- SI 2001/2885
- SI 2007/2734
- 2010/991 revoked.

The territorial extent is England and Wales. These Regulations supplement Chapter III of the Water Industry Act 1991 (c.56) (water supply). They also transpose requirements of Council Directive 98/83/EC on the quality of water intended for human consumption (OJ No L 330, 5.12.1998, p 32) and Council Directive 2013/51/Euratom laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (OJ No L 296, 7.11.2013, p 12). They are primarily concerned with the quality of water supplied in England by water undertakers and licensed water suppliers for domestic or food production purposes, and with arrangements for the publication of information about water quality. They revoke and replace the Water Supply (Water Quality) Regulations 2000 (SI 2000/3184). The regulations include detailed limits and analytical performance characteristics for a wide range of substances.

Parallel regulations, the Private Water Supplies (England) Regulations 2016, SI 618, for private supplies were made, brought into force 27 June 2016.²²⁸ They revoke and replace the Private Water Supplies Regulations 2009 (SI 2009/3101).

The Public and Private Water Supplies (Miscellaneous Amendments) (Scotland) Regulations 2017 were made in October 2017 brought into force 26 October 2017. These make amendments pursuant to the further implementation of Council Directive 98/83/EC on the quality of water intended for human consumption including, in particular, amendments made by Commission Directive (EU) 2015/1787 amending Annexes II and III to the Directive and Council Directive 2013/51/EURATOM with regard to radioactive substances in water intended for human consumption.²²⁹

Similar provisions were made in October 2017 in Northern Ireland by the Private Water Supplies Regulations (Northern Ireland) 2017²³⁰ and the Water Supply (Water Quality) Regulations (Northern Ireland) 2017,²³¹ and in Wales by the Private Water Supplies (Wales) Regulations 2017.²³²

²²⁷ http://www.legislation.gov.uk/ukxi/2016/614/pdfs/ukxi_20160614_en.pdf

²²⁸ <http://www.legislation.gov.uk/ukxi/2016/618/contents/made>

²²⁹ <http://www.legislation.gov.uk/ssi/2017/321/contents/made>

²³⁰ <http://www.legislation.gov.uk/nisr/2017/211/made>

²³¹ <http://www.legislation.gov.uk/nisr/2017/212/made>

²³² <http://www.legislation.gov.uk/wsi/2017/1041/made>

2.17 Psychoactive substances

The Psychoactive Substances Act 2016 received Royal Assent on 28 January 2016. The act applies across the UK and came into force on 26 May 2016.²³³

The act:

- Makes it an offence to produce, supply, offer to supply, possess with intent to supply, possess on custodial premises, import or export psychoactive substances; that is, any substance intended for human consumption that is capable of producing a psychoactive effect. The maximum sentence will be seven years' imprisonment;
- Excludes legitimate substances, such as food, alcohol, tobacco, nicotine, caffeine and medical products from the scope of the offence, as well as controlled drugs, which continue to be regulated by the Misuse of Drugs Act 1971;
- Exempts healthcare activities and approved scientific research from the offences under the act on the basis that persons engaged in such activities have a legitimate need to use psychoactive substances in their work;
- Includes provision for civil sanctions – prohibition notices, premises notices, prohibition orders and premises orders (breach of the two orders will be a criminal offence) – to enable the police and local authorities to adopt a graded response to the supply of psychoactive substances in appropriate cases;
- Provides powers to stop and search persons, vehicles and vessels, enter and search premises in accordance with a warrant, and to seize and destroy psychoactive substances.

Further information including explanatory notes is available as well as Home Office guidance for local authorities on taking action against “head shops” selling psychoactive substances, and Home Office guidance for retailers.²³⁴ Guidance is available from the Crown Prosecution Service on psychoactive substances in general and on assessing whether or not a substance is psychoactive. It is suggested that the suspected substance must be submitted to a Forensic Service Provider for analysis and identification. Separately, an expert witness should be asked to give an opinion as to whether the identified substance was capable of having a psychoactive effect based on analysis of the identified substance in a laboratory. That opinion will be based on a chemical reference standard produced as a result of that substance having been tested previously. Further detail about psychoactivity testing is set out in the Home Office's Forensic Strategy²³⁵ including on in-vitro receptor (e.g. opioid receptor) testing.

Certain enabling powers with UK applicability have also been made: the Psychoactive Substances Act 2016 (Consequential Amendments) Regulations 2016,²³⁶ the Psychoactive Substances Act 2016 (Commencement) Regulations 2016²³⁷ and the Magistrates' Courts (Psychoactive Substances Act 2016) (Transfer of Proceedings) Rules 2016.²³⁸

The Psychoactive Substances Act 2016 (correction slip) noted Schedule 5, paragraph 8(2): “1A” should read “1ZA”.²³⁹

²³³ <http://www.legislation.gov.uk/ukpga/2016/2/contents/enacted>

²³⁴ <https://www.gov.uk/government/publications/psychoactive-substances-act-guidance-for-retailers/psychoactive-substances-act-2016-guidance-for-retailers>

²³⁵ <https://www.gov.uk/government/publications/circular-0042016-psychoactive-substances-act-2016>

²³⁶ <http://www.legislation.gov.uk/uksi/2016/554/regulation/2/made>

²³⁷ <http://www.legislation.gov.uk/uksi/2016/553/contents/made>

²³⁸ <http://www.legislation.gov.uk/uksi/2016/546/made>

²³⁹ http://www.legislation.gov.uk/ukpga/2016/2/pdfs/ukpgacs_20160002_en.pdf

Regulation (EU) No 1307/2013²⁴⁰ establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy (Article 32(6)) provides that in order to prevent support payments being granted for illegal crops, areas used for the production of hemp may only be eligible if the varieties used have a tetrahydrocannabinol, THC, content in year on year testing not exceeding 0.2 %.

Commission Delegated Regulation (EU) 2017/1155 of 15 February 2017, published in June 2017 amended Delegated Regulation (EU) No 639/2014 as regards the control measures relating to the cultivation of hemp with regard to farm support payments (and other farm support measures not relevant to food or feed legislation).²⁴¹

Commission Recommendation (EU) 2016/2115²⁴² of 1 December 2016 has recommended monitoring for the presence of Δ^9 -tetrahydrocannabinol, its precursors and other cannabinoids in food of animal origin where there is evidence of animals being fed with feed containing hemp or hemp derived feed materials.²⁴³

Commission Implementing Regulation (EU) 2017/1172 of 30 June 2017²⁴⁴ amended Implementing Regulation (EU) No 809/2014 as regards the control measures relating to the cultivation of hemp to allow submission later in the year of official seed labels.

Council Implementing Decision (EU) 2017/1774 of 25 September 2017 imposed control measures as a new psychoactive substance on acryloylfentanyl, (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide). Acryloylfentanyl is a synthetic opioid structurally similar to fentanyl, a controlled substance widely used in medicine as an adjunct to general anaesthesia during surgery and for pain management. The available data suggest that acryloylfentanyl is a potent and long-lasting antinociceptive agent (reducing sensitivity to painful stimuli). Three Member States have collectively reported 47 deaths associated with acryloylfentanyl. In at least 40 deaths, acryloylfentanyl was the cause of death or is likely to have been a contributing cause of death. In addition, more than 20 acute intoxications suspected to be due to acryloylfentanyl have been reported. The United Kingdom is not bound by Decision 2005/387/JHA under which the above Decision is made.²⁴⁵

For similar reasons Council Implementing Decision (EU) 2017/2170 of 15 November 2017²⁴⁶ imposed control measures as a new psychoactive substance on N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl).

The Commission signalled its intention to the adopt a Directive of the European Parliament and of the Council amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA.²⁴⁷ This was done by Directive (EU) 2017/2103²⁴⁸ of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA.

²⁴⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1499100367442&uri=CELEX:02013R1307-20150603>

²⁴¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.167.01.0001.01.ENG&toc=OJ:L:2017:167:TOC

²⁴² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.327.01.0103.01.ENG&toc=OJ:L:2016:327:TOC

²⁴³ <https://www.efsa.europa.eu/en/efsajournal/pub/4141>

²⁴⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.170.01.0087.01.ENG&toc=OJ:L:2017:170:TOC

²⁴⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.251.01.0021.01.ENG&toc=OJ:L:2017:251:TOC

²⁴⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.306.01.0019.01.ENG&toc=OJ:L:2017:306:TOC

²⁴⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.359.01.0001.01.ENG&toc=OJ:C:2017:359:TOC

²⁴⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.305.01.0012.01.ENG&toc=OJ:L:2017:305:TOC

Regulation (EU) 2017/2101 of the European Parliament and of the Council of 15 November 2017 amended Regulation (EC) No 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances.

In November 2017 the Court of Appeal (Criminal Division) heard appeals on convictions of possessing a psychoactive substance, nitrous oxide, with intent to supply contrary to Section 7 of the Psychoactive Substances Act 2016. The grounds of appeal focused on nitrous oxide as a medicinal product and the exemption in the Psychoactive Substances Act for medicinal products as defined in the Human Medicines Regulations 2012. The court of appeal held that nitrous oxide could not be regarded as a medicinal product when used in the circumstances in which the applicants were found to possess it. Application for permission to appeal was refused.²⁴⁹ See also the Judgment of the Court (Fourth Chamber) of 10 July 2014 which found Article 1(2)(b) of Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC must be interpreted as not covering substances, such as those at issue in the main proceedings, which produce effects that merely modify physiological functions but which are not such as to have any beneficial effects, either immediately or in the long term, on human health, are consumed solely to induce a state of intoxication and are, as such, harmful to human health.²⁵⁰ I am indebted to 'Lexology'²⁵¹ for an alert to the above cases.

2.18 Herbal products and medicines

Herbal medicine has been practised in many countries for centuries with particularly strong and established traditions in some Asian countries, notably in China and India but also in Europe including the UK. In the UK, use of herbal medicines is common and it is estimated that up to 20% of the population use herbal products at some time in their lives.²⁵² Public Analysts, and hence the Government Chemist, may be called upon to examine herbal products, including herbal medicines. EU legislation on pharmaceutical products for human use also applies in general to traditional herbal medicines.²⁵³ However, in order to overcome difficulties encountered by Member States in applying pharmaceutical legislation to traditional herbal medicinal products in a uniform manner, a simplified registration procedure was introduced in 2004, Directive 2004/24/EC.²⁵⁴ A list of herbal substances, preparations and combinations for use in traditional herbal medicinal products has been established by Commission Decision 2008/911/EC of 21 November 2008.²⁵⁵ This list is periodically updated; see for example (non-exhaustively) Commission Implementing Decision (EU) 2016/1659 of 13 September 2016²⁵⁶ that introduced species of *Melaleuca* (Tea Tree oil) into the list.

In the UK Herbal medicines can be registered under the traditional herbal registration scheme and the Medicines and Healthcare products Regulatory Agency, MHRA, list of registered

²⁴⁹ Neutral Citation Number: [2017] EWCA Crim 1743, Case No: 201704033 B5, 201704131 B2, 201704393 C3 & 201704176 C5, [http://www.bailii.org/cgi-bin/format.cgi?doc=/ew/cases/EWCA/Crim/2017/1743.html&query=\(nitrous\)+AND+\(oxide\)+AND+\(psychoactive\)](http://www.bailii.org/cgi-bin/format.cgi?doc=/ew/cases/EWCA/Crim/2017/1743.html&query=(nitrous)+AND+(oxide)+AND+(psychoactive))

²⁵⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62013CA0358>

²⁵¹ <https://www.lexology.com/>

²⁵² Walker, D. R. (2015), Report on the Regulation of Herbal Medicines and Practitioners, 26 March 2015, http://www.dcs-science.net/Report_on_Regulation_of_Herbal_Medicines_and_Practitioners.pdf (Accessed 17.09.2016)

²⁵³ Directive 2001/83/EC <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474128484290&uri=CELEX:02001L0083-20121116>

²⁵⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474128379997&uri=CELEX:32004L0024>

²⁵⁵ http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm

²⁵⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1659>

traditional herbal medicines is updated regularly.²⁵⁷ A list of banned or restricted herbal products, including for example aconite, belladonna, kava-kava and ragwort, is available.²⁵⁸

Periodic assessment of herbal products takes place, for example recently the International Agency for Research on Cancer, IARC, of the WHO published an evaluation of carcinogenic risks to humans of some drugs and herbal medicines. Whole leaf extract of aloe vera, ginkgo biloba extract, goldenseal root powder, kava extract and the pulegone component of pennyroyal oils were classified in IARC Group 2B (possibly carcinogenic to humans).^{259, 260}

3 Consumer choice

This section covers (3.1) labelling, (3.2) dual quality products, (3.3) composition, (3.4) GMOs, (3.5) cloned animals, (3.6) novel foods, (3.7) consumer attitudes and (3.8) the Consumer Rights Act 2015.

3.1 Food labelling

The primary legislation is now Regulation 1169/2011²⁶¹ 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.²⁶² Domestic implementation is effected in England by the Food Information Regulations (SI 2014 No 1855),²⁶³ in Northern Ireland by the Food Information Regulations (Northern Ireland) 2014 (SR 2014 No 223)²⁶⁴ and, in Wales the Food Information Regulations (Wales) 2014 (SI 2014 No 2303, W227).²⁶⁵ In Scotland implementation is by the Food Information Regulations (Scotland) 2014 (SSI 312)²⁶⁶ which were amended in December 2015 by the Food Information (Miscellaneous Amendments) (Scotland) Regulations 2015 (SSI 410).²⁶⁷ These make a set of small drafting amendments, for example clarifying aspects of the labelling of “alcohol-free”, “dealcoholized” and “low alcohol” drinks.

Information is available on the Commission website.²⁶⁸ Guidance on nutrition labelling is also available on the Commission website.²⁶⁹

See also Section 3.3.4 on Regulation (EU) No 1308/2013 on a common organisation of the markets in agricultural products and in particular a case in the European Court that precludes the terms ‘milk’ and ‘milk product’ being applied to plant based liquids.

3.1.1 Country of origin labelling

The Country of Origin of Certain Meats (England) Regulations 2015 (SI 518)²⁷⁰ modified certain provisions of the Food Safety Act 1990, and implemented Articles 3 to 6 and 8 of Commission

²⁵⁷ <https://www.gov.uk/government/publications/herbal-medicines-granted-a-traditional-herbal-registration-thr>

²⁵⁸ <https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients>

²⁵⁹ <http://monographs.iarc.fr/ENG/Monographs/vol108/mono108.pdf>

²⁶⁰ Grosse et al. (2013), Carcinogenicity of some drugs and herbal products, *The Lancet Oncology*, 14, 807-808,

<http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045%2813%2970329-2/fulltext>

²⁶¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF>

²⁶² <http://www.reading.ac.uk/foodlaw/label/links.htm>

²⁶³ http://www.legislation.gov.uk/uksi/2014/1855/pdfs/uksi_20141855_en.pdf

²⁶⁴ http://www.legislation.gov.uk/nisr/2014/223/pdfs/nisr_20140223_en.pdf

²⁶⁵ http://www.legislation.gov.uk/wsi/2014/2303/pdfs/wsi_20142303_mi.pdf

²⁶⁶ http://www.legislation.gov.uk/ssi/2014/312/pdfs/ssi_20140312_en.pdf

²⁶⁷ http://www.legislation.gov.uk/ssi/2015/410/pdfs/ssi_20150410_en.pdf

²⁶⁸ https://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation_en

²⁶⁹ http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm

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.²⁷¹

Similar legislation has been enacted in Northern Ireland through The Country of Origin of Certain Meats Regulations (Northern Ireland) 2015²⁷² (SR 321) and in Wales by the Country of Origin of Certain Meats (Wales) Regulations 2015²⁷³ (SI 1591, W177).

FSA in Northern Ireland in late March 2016 issued some clarification on voluntary labelling of Country of Origin. European food labelling legislation Regulation (EU) No. 1169/2011 on Food Information to Consumers introduced in December 2014 sets out requirements for “voluntary labelling” – including country of origin – stating that any additional voluntary claims must not mislead, be ambiguous or confuse consumers. The FSA in NI note that using the additional voluntary term “Irish” on food produced in Northern Ireland may be misleading to consumers as this term is also used to describe another member state of the EU. However, whether or not the use of the term “Irish” in food labelling is misleading, can only be determined by a court of law. The FSA continues to advise local authorities in Northern Ireland on a case by case basis. Ultimately it is the food manufacturers’ responsibility not to mislead consumers with the labelling information that they provide.²⁷⁴

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, for drawing attention to this).²⁷⁵

3.1.3 Direct sale to the consumer

See Section 0 for a case in the European Court on the meaning of sale *directly to the final consumer or user* in the context of Article 28(2) of Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling.

3.1.4 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).²⁷⁶

²⁷⁰ http://www.legislation.gov.uk/uksi/2015/518/pdfs/uksi_20150518_en.pdf

²⁷¹ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2015>

²⁷² http://www.legislation.gov.uk/nisr/2015/321/pdfs/nisr_20150321_en.pdf

²⁷³ http://www.legislation.gov.uk/wsi/2015/1519/pdfs/wsi_20151519_mi.pdf

²⁷⁴ <https://www.food.gov.uk/northern-ireland/news-updates/news/2016/15025/voluntary-labelling-of-country-of-origin>

²⁷⁵ http://ec.europa.eu/fisheries/documentation/publications/eu-new-fish-and-aquaculture-consumer-labels-pocket-guide_en.pdf

²⁷⁶ <https://www.gov.uk/guidance/food-labelling-giving-food-information-to-consumers>

3.1.5 Organic food

The principal measure is Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products. Detailed rules for the implementation of Regulation 834/2007 are given in Commission Regulation (EC) No 889/2008 of 5 September 2008²⁷⁷ which is amended fairly regularly hence the consolidated version at time or writing is cited but EUR-Lex should be consulted for the most up-to-date version.

Annex III to Commission Regulation (EC) No 1235/2008 sets out the list of third countries whose systems of production and control measures for organic production of agricultural products are recognised as equivalent to those laid down in Regulation (EC) No 834/2007. The regulation is successively updated and the latest version on EUR Lex should be consulted.

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. A Defra list of UK approved organic control bodies is available.²⁷⁸

Commission Implementing Regulation (EU) 2016/1842 of 14 October 2016 amended Regulation (EC) No 1235/2008 including on electronic certificates of inspection for imported organic products, and Regulation (EC) No 889/2008 on requirements for preserved or processed organic products and the transmission of information. This was to reduce divergent application of control measures by member States.²⁷⁹

Commission Implementing Regulation (EU) 2017/838 of 17 May 2017 amended Regulation (EC) No 889/2008 as regards feed for certain organic aquaculture animals. Under Regulation (EC) No 889/2008, the animals concerned are to be fed with feed naturally available in ponds and lakes but permits the use of organic feed of plant origin or seaweed where natural feed resources are not available in sufficient quantities and establishes maximum percentages of fishmeal and fish oil that can be included in the feed ration of siamese catfish and shrimps where naturally available feed is supplemented. Naturally occurring feed is limited or non-existent in the hatchery stage and the rules on feeding penaeid shrimps, in particular Tiger shrimp (*Penaeus monodon*) would lead to malnutrition and increased mortality if applied in the juvenile stages in a hatchery environment. The Regulation is amended accordingly.²⁸⁰

Commission Implementing Regulation (EU) 2017/1473 of 14 August 2017 amended Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 to remove 'Bolicert Ltd' from the list of control authorities and control bodies competent to carry out controls and issue certificates in third countries for the purpose of organic equivalence.²⁸¹

A Commission Decision of 16 August 2017 (2017/C 273/03) notes Decision 2009/427/EC establishing an expert group for technical advice on organic production and extends from three to four years the term of membership, which may be renewed for not more than three terms.²⁸² Commission Decision 2017/C 287/03 of 30 August 2017²⁸³ lists the names of the members of the group.

²⁷⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1517335185113&uri=CELEX:02008R0889-20180101>

²⁷⁸ <https://www.gov.uk/government/publications/organic-certification-list-of-uk-approved-organic-control-bodies>

²⁷⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.282.01.0019.01.ENG&toc=OJ:L:2016:282:TOC

²⁸⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0838>

²⁸¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.210.01.0004.01.ENG&toc=OJ:L:2017:210:TOC

²⁸² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.273.01.0003.01.ENG&toc=OJ:C:2017:273:TOC

²⁸³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.287.01.0003.01.ENG&toc=OJ:C:2017:287:TOC

Commission Implementing Regulation (EU) 2017/1862 of 16 October 2017²⁸⁴ amended Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 on imports of organic products from third countries by extending the period for control bodies and authorities to submit requests for recognition to 31 October 2018. Commission Implementing Regulation (EU) 2017/2329 of 14 December 2017 further amended and corrected Regulation 1235/2008 on the arrangements for imports of organic products from third countries including Costa Rica, Japan, New Zealand, the Republic of Korea, Albania, Turkey, Indonesia and others.²⁸⁵

Commission Implementing Regulation (EU) 2017/2273 of 8 December 2017 amended Regulation (EC) No 889/2008 to extend the period during which non-organically reared pullets for egg production of not more than 18 weeks can be brought into an organic livestock unit. Also extended is the period during which a maximum of 5 % of non-organic protein feed can be used for porcine and poultry species raised on organic farms. The extensions are to 31 December 2018 and arise owing to lack of sufficient availability of their organic equivalents.²⁸⁶

Article 28 of Regulation 834/2007 imposes conditions of notification to the competent authorities and submission to a control body on any operator who trades in organic products from a third country. However (Art. 28(2)) Member States may exempt operators who (with provisos) sell products *directly to the final consumer or user*. The meaning of the later phrase was tested before the European Court, Case C-289/16,²⁸⁷ which ruled that Article 28(2) must be interpreted as meaning that, in order for products to be regarded as being sold ‘directly’, within the meaning of that provision, to the final consumer or user, it is necessary for the sale to occur in the presence of both the operator or his sales personnel and the final consumer. The author of the present report wonders if this may have implications for the interpretation of ‘prepacked for direct sale’ in Regulation 1169/2011 (Food Information to Consumers)?

Council Decision (EU) 2017/2307 of 9 October 2017 noted the conclusion of an Agreement between the European Union and the Republic of Chile on trade in organic products to recognise the equivalence of their respective rules on organic production and control systems as regards organic products.²⁸⁸ The full text of the Agreement is available.²⁸⁹

3.1.6 Net Quantities

Minor corrections were made to the Weights and Measures (Food) (Amendment) Regulations (Northern Ireland) 2016 No. 187 that originally came into operation on 18 April 2016. These Regulations remove provisions from weights and measures law applying in Northern Ireland that overlap or conflict with Regulation (EU) No 1169/2011 (provision of food information to consumers, FIC) and enable the enforcement of certain provisions of the FIC that relate to net quantity. An extensive explanatory note accompanies the main regulations.²⁹⁰

²⁸⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.266.01.0001.01.ENG&toc=OJ:L:2017:266:TOC

²⁸⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.333.01.0029.01.ENG&toc=OJ:L:2017:333:TOC

²⁸⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.326.01.0042.01.ENG&toc=OJ:L:2017:326:TOC

²⁸⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.412.01.0010.01.ENG&toc=OJ:C:2017:412:TOC

²⁸⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.331.01.0001.01.ENG&toc=OJ:L:2017:331:TOC

²⁸⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.331.01.0004.01.ENG&toc=OJ:L:2017:331:TOC

²⁹⁰ The Weights and Measures (Food) (Amendment) Regulations (Northern Ireland) 2016, No. 187 and correction slip, <http://www.legislation.gov.uk/nisr/2016/187/regulation/1/made>

3.1.7 Protected names and quality schemes

There are three protection marks in the EU:²⁹¹

- 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.²⁹²

Council Decision (EU) 2017/1912 of 9 October 2017²⁹³ established Agreement²⁹⁴ between the EU and Iceland on the protection of geographical indications for agricultural products and foodstuffs.

Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 sets out the rules on quality schemes for agricultural products and foodstuffs, including PGI, PDO and TSG.²⁹⁵

3.2 Dual quality products

In September 2017 the Commission issued a notice (2017/C 327/01)²⁹⁶ on the application of EU food and consumer protection law to the dual quality of food products. The notice stated that free movement of goods is one of the four fundamental freedoms of the Single Market but does not necessarily mean that every product must be identical in every corner of the Single Market. Whilst consumers are free to buy the products of their choice, business operators are also free to market and sell goods with different composition or characteristics, provided that they fully respect EU legislation (whether on the safety of products, labelling or other horizontal or sectoral legislation). However, a source of concern can be when the different composition of identically branded goods has the potential to mislead the consumer.

The issue of certain dual quality products, and in particular food products, has been a source of growing concern. In March 2017, the European Council welcomed action by the Commission to take the issue further. This action combines dialogue with the parties concerned and practical steps to enable concrete measures to be taken by the responsible authorities. The Joint Research Centre is working on guidelines for a common testing methodology, as a step towards comparable and authoritative tests across the EU. This is essential to assess the magnitude of the issue, and to provide the sound evidence basis required for action to be taken. A Code of Conduct for producers is being discussed to set out standards to be respected to prevent dual quality problems. The Commission has also been looking at enforcement of relevant EU legislation together with national consumer protection and food authorities.

The current notice lists the relevant legislation, general food law, (Regulation 178/2002), the food information to consumers' regulation (Regulation 1169/2011) and the unfair commercial practices directive (Directive 2005/29/EC) as well as product specific law such as on chocolate, jam and fruit juice. The notice discusses the interaction between such measures and gives advice on their

²⁹¹ http://ec.europa.eu/agriculture/quality/schemes/index_en.htm

²⁹² <https://www.gov.uk/guidance/eu-protected-food-names-how-to-register-food-or-drink-products>

²⁹³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.274.01.0001.01.ENG&toc=OJ:L:2017:274:TOC

²⁹⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.274.01.0003.01.ENG&toc=OJ:L:2017:274:TOC

²⁹⁵ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1488746464115&uri=CELEX:02012R1151-20130103>

²⁹⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.327.01.0001.01.ENG&toc=OJ:C:2017:327:TOC

application, including cross border cooperation and a flow chart to help assess unfair business practices in the case of branded food products.

3.3 Composition

3.3.1 Casein and caseinates

Directive (EU) 2015/2203 of the European Parliament and of the Council of 25 November 2015 brought up to date the approximation of the laws of the Member States relating to caseins and caseinates intended for human consumption and repeals Council Directive 83/417/EEC.²⁹⁷ The Directive defines the production, composition and labelling of casein and caseinates and stems from an international standard for edible casein products by the *Codex Alimentarius* Commission ('Codex standard for edible casein products').²⁹⁸ Domestic implementation was formalised in late 2016 by the Caseins and Caseinates (Wales) Regulations 2016 No.1130 (W.270)²⁹⁹ and the Caseins and Caseinates Regulations (Northern Ireland) 2016 No.415.³⁰⁰ The Caseins and Caseinates (Scotland) Regulations 2016 No.383³⁰¹ were made but were replaced on 15 December 2016 by the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016³⁰² owing to defects in S.S.I. 2016/383.

Domestic implementation of Directive (EU) 2015/2203 was completed in July 2017 in England by the Caseins and Caseinates (England) Regulations 2017 which came into force on 26 September 2017.³⁰³

Previous measures on caseins in each country of the UK are revoked. The compositional criteria include minimum milk protein in dry matter, minimum content of casein in milk protein (95.0% m/m), maximum water content, maximum milkfat, ash, maximum lactose and pH.

3.3.2 International Standards for Fruit and Vegetables

These publications provide illustrations and commentary that facilitate the common interpretation of standards in force regarding the quality of various fruits and vegetables being traded internationally. They are published under the Scheme for the Application of International Standards for Fruit and Vegetables set up by the OECD in 1962.³⁰⁴

3.3.3 Honey

The making and coming into force of the Honey (Wales) Regulations 2015³⁰⁵ (SI 1507, W174) completed the updating of domestic implementation of Council Directive 2001/110/EC relating to honey.³⁰⁶ These regulations sit alongside the Honey (Scotland) Regulations 2015 (SSI 208),³⁰⁷

²⁹⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1481228098768&uri=CELEX:32015L2203>

²⁹⁸ Codex Alimentarius Standard For Edible Casein Products CODEX STAN 290-1995 http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCODEX%2BSTAN%2B290-1995%252FCXS_290e.pdf

²⁹⁹ <http://legislation.data.gov.uk/wsi/2016/1130/contents/made/data.htm?wrap=true>

³⁰⁰ <http://www.legislation.gov.uk/nisr/2016/415/contents/made>

³⁰¹ http://www.legislation.gov.uk/ssi/2016/383/pdfs/ssi_20160383_en.pdf

³⁰² http://www.legislation.gov.uk/ssi/2016/422/pdfs/ssi_20160422_en.pdf

³⁰³ <http://www.legislation.gov.uk/ukxi/2017/848/note/made>

³⁰⁴ http://www.oecd-ilibrary.org/agriculture-and-food/international-standards-for-fruit-and-vegetables_19935668

³⁰⁵ http://www.legislation.gov.uk/wsi/2015/1507/pdfs/wsi_20151507_mi.pdf

³⁰⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1445979649018&uri=CELEX:02001L0110-20140623>

³⁰⁷ <http://www.legislation.gov.uk/ssi/2015/208/contents/made>

the Honey Regulations (Northern Ireland) 2015 (SR 261),³⁰⁸ and the Honey Regulations (England) 2015³⁰⁹ (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 24 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.

A coordinated control plan to assess the prevalence on the market of honey adulterated with sugars and honeys mislabelled with regard to their botanical source or geographical origin is described on the Commission website.³¹⁰ The non-compliances detected by the Member States were mostly related to the declaration of the botanical source (7%) and to adulteration with sugar (6%). Non-compliances related to the declaration of the geographical origin were less frequent (2%). Some non-compliances related to the botanical source are probably unintentional and the result of bees foraging a wide variety of plants, despite the hives being very close to the plant species identified as the botanical source. Member States also submitted to the Commission Joint Research Centre, JRC,³¹¹ 893 samples of honey which they had found to be compliant or suspicious. The JRC applied liquid chromatography-isotope ratio mass spectrometry, which can better distinguish different sugars than current validated methods. The findings³¹² were that 14 % of the samples they tested contained added sugar. This was further broken down according to geographical origin, point of collection (i.e. producer, packager or retailer) and type of honey. Overall, the results from the honey coordinated control plan indicate that the practice of adding sugars to honey is occurring, both within the EU and in third countries. The Commission will discuss with the relevant stakeholders an appropriate follow-up to this control plan.

The New Zealand Ministry for Primary Industries has published scientific definition for New Zealand mānuka honey.³¹³

3.3.4 Marketing of agricultural products

Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishes a common organisation of the markets in agricultural products.³¹⁴

This is an extensive piece of legislation that covers the following commodity sectors: cereals, rice, sugar, dried fodder, seeds, hops, olive oil and table olives, flax and hemp, fruit and vegetables, processed fruit and vegetable products, wine, live trees and other plants, bulbs, roots and the like, cut flowers and ornamental foliage, tobacco, beef and veal, milk and milk products, pigmeat, sheepmeat and goatmeat, eggs, poultrymeat, ethyl alcohol of agricultural origin, apiculture

³⁰⁸ <http://www.legislation.gov.uk/nisr/2015/261/contents/made>

³⁰⁹ http://www.legislation.gov.uk/ukxi/2015/1348/pdfs/ukxi_20151348_en.pdf

³¹⁰ https://ec.europa.eu/food/safety/official_controls/food_fraud/honey_en

³¹¹ <https://ec.europa.eu/jrc/en>

³¹² https://ec.europa.eu/food/sites/food/files/safety/docs/oc_control-progs_honey_jrc-tech-report_2016.pdf

³¹³ <https://www.mpi.govt.nz/growing-and-producing/bees-and-other-insects/manuka-honey/>

³¹⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32013R1308>

products, silkworms, and other products. The Single Common Market Organisation (Consequential Amendments) Regulations 2013³¹⁵ make appropriate changes to a wide range of domestic law including, for example, the Drinking Milk (England) Regulations, the Poultrymeat (England) Regulations, and the Spreadable Fats (Marketing Standards) Regulations. A correction slip was issued in September 2016³¹⁶ amending minor drafting errors in the 2013 regulations.

Regulation (EU) 2017/2393 of the European Parliament and of the Council of 13 December 2017 amended a number of Regulations mainly concerning the common agricultural policy, but also 1308/2013. Annex III of Regulation (EU) 2017/2393 amended Annexes VII and VIII to Regulation 1308/2013 in relation to its Annex VII, on the upper limit for the total alcoholic strength which may now exceed 15 % volume for wines with a protected designation of origin which have been produced as detailed in the amendment. The measure also made minor changes in Annex VIII for years when climatic conditions have been exceptionally unfavourable for wine.³¹⁷

The European Court (Seventh Chamber) on 14 June 2017 gave a preliminary ruling with regard to the sales descriptions 'milk' and 'milk products'. The case was referred from a German court where the Applicant was Verband Sozialer Wettbewerb eV, a German association safeguarding competition, and the Defendant was TofuTown.com GmbH. The ECJ held that Regulation 1308/2013 (Article 78(2) and Annex VII, Part III) must be interpreted as precluding the term 'milk' and the designations reserved by that regulation exclusively for milk products from being used to designate a purely plant based product in marketing or advertising, even if those terms are expanded upon by clarifying or descriptive terms indicating the plant origin of the product at issue, unless that product is listed in Annex I to Commission Decision 2010/791/EU of 20 December 2010 listing the products referred to in the second subparagraph of point III(1) of Annex XII to Council Regulation (EC) No 1234/2007.³¹⁸

3.3.5 Free range eggs

Commission Regulation (EC) No 589/2008 (2) lays down detailed rules for implementing Council Regulation (EC) No 1234/2007 (which was repealed and replaced by Regulation (EU) No 1308/2013) as regards marketing standards for eggs. Commission Delegated Regulation (EU) 2017/2168 of 20 September 2017³¹⁹ amended Regulation (EC) No 589/2008 as regards marketing standards for free range eggs where hens' access to open air runs is restricted.

3.3.6 Meat and meat products

Definitions of 'meat', 'meat product', 'meat preparation', 'minced meat, and 'mechanically separated meat' are found in Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for on the hygiene of foodstuffs.

The Products Containing Meat etc. Regulations 2014 enacted in England (e.g. SI 3001/2014³²⁰), Scotland, Wales and Northern Ireland lay down definitions and minimum meat content standards for certain meat products presented for sale directly to the consumer (see our report for October – December 2014).³²¹

³¹⁵ http://www.legislation.gov.uk/ukxi/2013/3235/pdfs/ukxi_20133235_en.pdf

³¹⁶ <http://www.legislation.gov.uk/ukxi/2013/3235/made>

³¹⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.350.01.0015.01.ENG&toc=OJ:L:2017:350:TOC

³¹⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.277.01.0018.01.ENG&toc=OJ:C:2017:277:TOC

³¹⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.306.01.0006.01.ENG&toc=OJ:L:2017:306:TOC

³²⁰ http://www.legislation.gov.uk/ukxi/2014/3001/pdfs/ukxi_20143001_en.pdf

³²¹ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review>

Similar Regulations have been enacted in Scotland with the Products Containing Meat etc. Regulations (Scotland) Regulations 2014 (SSI 289/2014)³²² 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) 2014³²³ (SR 285/2014).

There was a technical amendment to the Scottish regulations inserting a reference to section 22 of the Food Safety Act 1990 (defence of publication in the course of business) by the Products Containing Meat etc. (Scotland) Amendment Regulations 2016 (SSI 24/2016).³²⁴

A series of cases on 'desinewed meat' (DSM) and mechanically separated meat (MSM) reached the Court of Appeal with judgement given in May 2017. In essence an English firm, Newby Foods Ltd, sought to distinguish its product DSM from MSM. The first stage of the Newby process forces meat bearing bones into contact with each other so that meat is removed from the bones by shearing forces. In a second stage the meat removed in this way is then passed through a second machine, which is effectively a mincer, producing a product which looks like minced meat. This meat product was known in the UK as desinewed meat regarded by many, including formerly the FSA, as distinct from MSM. However the Commission maintains that DSM is MSM, and threatened to take action against the UK if DSM continued to be produced and sold without regard to the restrictions imposed upon MSM. This action could have involved "safeguard measures", restricting the export of UK meat products to the rest of the EU. Notwithstanding the fact that it disagreed with the Commission's classification of DSM as MSM, on 4 April 2012 the FSA issued a moratorium with the result that DSM could no longer be produced from beef and lamb bones, and could only be produced from chicken and pork bones if it were classified and labelled as MSM and not counted towards the meat content of products in which it was present. Newby brought proceedings and the High Court allowed that certain chicken and pork products manufactured by Newby should not be classified as MSM. However the High Court also made a preliminary reference to the European Court asking a series of questions that the ECJ amalgamated as:

...whether points 1.14 and 1.15 of Annex I to Regulation No 853/2004, which contain the definitions of ... 'mechanically separated meat' and 'meat preparations' respectively, must be interpreted as meaning that the product obtained by the mechanical removal of meat from flesh-bearing bones after boning or from poultry carcasses must be classified as 'mechanically separated meat' within the meaning of that point 1.14 only where the process used results in a loss or modification of the muscle fibre structure which is significant, while the classification as 'meat preparations' within the meaning of point 1.15 must be chosen where that loss or modification is not significant. Secondly, in the event that that interpretation should prevail, the referring court seeks to ascertain what degree of modification or loss is required for that modification or loss to have to be regarded as significant and what process should be used in order to determine whether the degree thus required has been attained.

The ECJ held that the relevant provisions must be interpreted as meaning that the [Newby] product must be classified as 'mechanically separated meat' and cannot be classified as a 'meat preparation'. In the light of this the FSA appealed the High Court judgement which the Court of

³²² http://www.legislation.gov.uk/ssi/2014/289/pdfs/ssi_20140289_en.pdf

³²³ http://www.legislation.gov.uk/nisr/2014/285/pdfs/nisr_20140285_en.pdf

³²⁴ http://www.legislation.gov.uk/ssi/2016/24/pdfs/ssi_20160024_en.pdf

Appeal allowed, further concluding that the European Court judgement, properly understood, was conclusive and left no scope for argument as to the application of the law to the facts. It was not open to conclude that the products of Newby's process are not MSM.

The interested reader is advised to consider the full judgements:

Judgment of the Court (Tenth Chamber) 16 October 2014, Case C-453/13, Request for a preliminary ruling under Article 267 TFEU from the High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court) (United Kingdom), in the proceedings The Queen, on the application of: Newby Foods Ltd v Food Standards Agency,³²⁵ and Case No: C1/2016/2112, In the Court of Appeal (Civil Division) on Appeal From High Court, Queen's Bench Division, Administrative Court, Mr. Justice Edwards-Stuart, CO69232012, (Jones, LJ, Beatson LJ and Moyland LJ).³²⁶

3.3.7 Olive oil and table olives

Pursuant to Article 91 of Regulation (EU) No 1308/2013 on the common organisation of the markets in agricultural products, Commission Regulation (EEC) No 2568/91 defines the chemical and organoleptic characteristics of olive and olive-pomace oil, and lays down methods of assessing those characteristics. Regulation (EEC) No 2568/91 methods are regularly updated in line with the work of the International Olive Council. The Olive Oil (Marketing Standards) Regulations 2014, which apply to the whole of the UK, and for which a correction slip has been issued (September 2016) implement the above.³²⁷ The general position of the Commission as regards upcoming International Olive Council analytical matters was set out in Council Decision (EU) 2016/1080 of 27 June 2016.³²⁸ Guidance on olive oil composition, characteristics and labelling is available from Defra.³²⁹

A corrigendum was issued on 26 September 2016 to Commission Delegated Regulation (EU) 2016/2095 amending Regulation (EEC) No 2568/91 on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis. Certain limits for purity characteristics were corrected.³³⁰

3.3.8 Spices

The British Retail Consortium (BRC), Food and Drink Federation (FDF) and Seasoning and Spice Association (SSA) in liaison with the FSA and FSS have issued guidance for food companies that use culinary dried herbs and spices with information on best practice in assessing and protecting the authenticity of these products.^{331, 332}

3.3.9 Spirit drinks etc.

Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008

³²⁵ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1505653462283&uri=CELEX:62013CJ0453>

³²⁶ <http://www.bailii.org/ew/cases/EWCA/Civ/2017/400.html>

³²⁷ <http://origin-www.legislation.gov.uk/ukxi/2014/195/contents/made>

³²⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1080>

³²⁹ <https://www.gov.uk/guidance/olive-oil-regulations-and-inspections>

³³⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.211.01.0058.01.ENG&toc=OJ:L:2017:211:TOC

³³¹ <https://www.fdf.org.uk/news.aspx?article=7539>

³³² <https://www.fdf.org.uk/herbs-spices-guidance.aspx>

controls the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks.³³³ Commission Regulation (EC) No 2870/2000³³⁴ lists and describes the reference methods for the analysis of spirit drinks.

The Commission aims better to align the existing Regulation (EC) No 110/2008 on spirit drinks with the Treaty on the Functioning of the European Union. In June 2017 the European Economic and Social Committee published³³⁵ a generally supportive opinion on the proposal. On presentation and labelling, the Committee suggested avoiding any kind of misrepresentation or misunderstanding in relation to 'imitation flavours'; Article 8(5) of the Commission proposal specifies that the sales denominations supplemented by the term 'flavour' (or any other similar terms) may be used to refer to flavourings that imitate a spirit drink or their use in the production of a foodstuff other than a beverage. The Committee considered that this provision could be misleading for consumers. The Committee also requested strengthened arrangements to allow fake spirits to be removed from the market.

3.3.10 Wine

Wine law is complex and extensive; a readable guide is on the FSA website with links to European legislation.³³⁶ Regulation 1308/2013 on the common organisation of the markets in agricultural products also applies, (see Section 3.3.4). There is no ready compendium of EU legislation on wine.

A search of EUR-Lex for 'wine' yields an unmanageable number of hits however it is possible to narrow this down by selecting legislation and searching on a year by year basis.

Recent updates include Commission Delegated Regulation (EU) 2017/670³³⁷ of 31 January 2017, published in April 2017, supplementing Regulation (EU) No 251/2014³³⁸ on authorised production processes for aromatised wine products, which includes, for example, vermouth and sangria. Regulation 2017/670 updates the production processes recommended and published by the International Organisation of Vine and Wine, OIV³³⁹ which provides much useful information including methods of analysis.

Commission Delegated Regulation (EU) 2017/1353 of 19 May 2017 amended Regulation (EC) No 607/2009 as regards the wine grape varieties and their synonyms that may appear on wine labels. The regulation seeks to resolve a dispute between Croatia and Slovenia on use of the wine grape variety name 'Teran'.³⁴⁰

Commission Implementing Regulation (EU) 2017/2281 of 11 December 2017 authorised an increase of the limits for the enrichment of wine produced using the grapes harvested in 2017 in certain wine-growing regions of Germany and in all wine-growing regions of Denmark, the Netherlands and Sweden owing to exceptionally unfavourable climatic conditions.³⁴¹

See also Section 3.3.4.

³³³ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474277348569&uri=CELEX:02008R0110-20160705>

³³⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1499102421377&uri=CELEX:02000R2870-20160426>

³³⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.209.01.0054.01.ENG&toc=OJ:C:2017:209:TOC

³³⁶ <https://www.food.gov.uk/business-industry/winestandards/lawguide>

³³⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.097.01.0005.01.ENG&toc=OJ:L:2017:097:TOC

³³⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498062395786&uri=CELEX:02014R0251-20140327>

³³⁹ <http://www.oiv.int/>

³⁴⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.190.01.0005.01.ENG&toc=OJ:L:2017:190:TOC

³⁴¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.328.01.0017.01.ENG&toc=OJ:L:2017:328:TOC

3.3.11 Water in frozen poultry

As with all animal species, poultry contains naturally present water, known as the 'physiological water'. Commercial processing in accordance with good manufacturing practice adds an amount of technically unavoidable water known as 'extraneous water'. European legislation³⁴² sets limits for 'extraneous water' so that consumers are not being disadvantaged by excess 'extraneous water' in poultry meat they purchase.

A study funded by the European Commission and undertaken by LGC³⁴³ has provided a comprehensive account of the current technologies used in the processing of poultry in the EU and the amount of technologically unavoidable water added to broiler chickens by different chilling methods.

The results obtained showed that the largest observed effect on the water/protein ratio was for portion type, with 'breast' behaving very differently to 'leg' and 'carcase'. Chilling method did not have a significant effect on 'breast' and provides evidence for retention of a single legal limit for breast fillet. Immersion chilling adds significantly more water to 'leg' and 'carcase' than any other chilling method. This provides evidence for retention of a separate legal limit for immersion chilled carcasses but there is no strong evidence to require different limits for the other four chilling methods. 'Leg' also behaved very similarly to 'carcase' in this study. Thus it would be prudent to retain a separate legal limit for immersion chilled leg. Although this study has provided valuable information, data sets for some of the variables studied were small owing to the unavailability of some of the required samples, hence the results from this study should be treated with caution in considering future legislative limits.³⁴⁴

An interesting court case on water in poultry came before the (European) Court of Justice (Fourth Chamber) with judgement given on 9 March 2017. This was a request for a preliminary ruling from a French court on Regulation (EC) No 543/2008 – Article 15(1) – Article 16 – Frozen or quick-frozen chickens – Maximum limit for water content. The questions for the court were as follows:³⁴⁵

1. Does compliance with the water-content threshold laid down by Article 15 of Regulation (EC) No 543/2008, in conjunction with Annexes VI and VII thereto, constitute a requirement of 'sound and fair marketable quality' within the meaning of Article 28(1) of Commission Regulation (EC) No 612/2009 and of the judgment of the Court of Justice in *Nowaco Germany* (C-353/04, EU:C:2006:522)?
2. Can frozen poultry with a water content exceeding the threshold laid down by Article 15 of Regulation (EC) No 543/2008, in conjunction with Annexes VI and VII thereto, accompanied by a health certificate issued by the competent authority, be marketed within the European Union in normal conditions, within the meaning of Article 28 of Regulation (EC) No 612/2009, and, if so, in what conditions?
3. Is the fact that the water-content threshold remains at 5.1 % under Annex VI to Regulation (EC) No 543/2008, and has not been revised for several decades, despite alleged changes

³⁴² Regulation (EU) No 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1501780319097&uri=CELEX:02013R1308-20170801> and Commission Regulation (EC) No 543/2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultrymeat: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R0543>.

³⁴³ <http://www.lgcgroup.com/about-us/media-room/latest-news/2017/lgc-completes-study-to-establish-uptake-of-water-d/#.WUzKHbpFxmU>

³⁴⁴ https://ec.europa.eu/agriculture/sites/agriculture/files/external-studies/2016-water-in-poultrymeat/final-report_en.pdf

³⁴⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2015.190.01.0004.01.ENG&toc=OJ:C:2015:190:TOC

- in rearing practices and criticism in certain scientific studies that that threshold is obsolete, compatible or incompatible with EU law, and in particular with the principle of legal certainty?
4. Are Annexes VI and VII to Regulation (EC) No 543/2008 sufficiently precise for the checks provided for by Article 15 of that regulation to be carried out, or was France under an obligation to lay down 'practical measures for the checks' 'at all stages of marketing', failing which checks carried out at the stage of exportation of the goods cannot be relied upon?
 5. Can the requests for counter-analyses which are provided for by Article 16(2) and (5) of Regulation No 543/2008 in respect of the results of slaughterhouse checks be extended to checks carried out at the stage of marketing of export products, in the presence of the parties, pursuant to, inter alia, Article 41 of the Charter of Fundamental Rights of the European Union?

The judgement of the Court of Justice³⁴⁶ upheld the current law and confirmed that frozen or quick-frozen chickens with a water content exceeding the limits are not marketable in the EU and do not satisfy the requirement of sound and fair marketable quality. However the Court affirmed that an exporter of frozen or quick-frozen chickens may be present or represented when the goods are examined and when samples are taken and may request a further examination or sampling of the goods if he considers that the results obtained by the competent authorities are not valid.

The Court summarised its findings thus:³⁴⁷

1. The examination of the third question did not bring to light any evidence able to affect the validity of the limits for water content in frozen chicken meat laid down in Article 15(1) and Annexes VI and VII to Commission Regulation (EC) No 543/2008 of 16 June 2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultrymeat, as amended by Commission Implementing Regulation (EU) No 1239/2012 of 19 December 2012.
2. Article 28(1) of Commission Regulation (EC) No 612/2009 of 7 July 2009 on laying down common detailed rules for the application of the system of export refunds on agricultural products, as amended by Commission Regulation (EU) No 173/2011 of 23 February 2011, must be interpreted as meaning that frozen or quick-frozen chickens with a water content exceeding the limits set by Regulation No 543/2008, as amended by Implementing Regulation No 1239/2012, are not marketable in normal conditions on the territory of the European Union and do not satisfy the requirement of sound and fair marketable quality, even if they are accompanied by a health certificate issued by the competent authority.
3. Since Annexes VI and VII to Regulation No 543/2008, as amended by Implementing Regulation No 1239/2012, are sufficiently precise for the purpose of carrying out the checks on frozen and quick-frozen chickens intended for export with export refunds, the fact that a Member State has not adopted practical measures, whose adoption is provided for in Article 18(2) of that regulation, does not prevent those checks from being relied on against the undertakings concerned.
4. An exporter of frozen or quick-frozen chickens may, in accordance with Article 118(2) and Article 119(1), second subparagraph, of Regulation (EC) No 450/2008 of the European Parliament and of the Council of 23 April 2008 laying down the Community Customs Code (Modernised Customs Code) may, first, be present or represented when the goods are examined and when samples are taken and, second, may request a further examination or

³⁴⁶ <http://curia.europa.eu/juris/document/document.jsf?docid=188754&doclang=en>

³⁴⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.144.01.0002.01.ENG&toc=OJ:C:2017:144:TOC#ntr1-C_2017144EN.01000201-E0001

sampling of the goods if he considers that the results obtained by the competent authorities are not valid.

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.³⁴⁸

Commission Implementing Decisions on GMOs are recorded in relevant updates of this section but are not retained in the text going forward. For a register of EU authorised GMOs and those withdrawn from the market see the GMO register on the Commission website.³⁴⁹ Labelling, environmental and post-market monitoring, a detection method and reference material are normally detailed in the Decisions.

Pursuant to Regulation (EC) No 1829/2003 four soybean and three oilseed rape GMOs were authorised and one maize GMO authorisation was renewed on 21 December 2017. Details are given below.

Commission Implementing Decision (EU) 2017/2448 of 21 December 2017³⁵⁰ authorised the placing on the market (but not cultivation) of products containing, consisting of, or produced from genetically modified soybean 305423 x 40-3-2 (DP-3Ø5423-1 x MON-Ø4Ø32-6). This GMO has a reduced expression of the soybean enzyme omega-6 desaturase, which results in a high oleic acid and reduced linoleic acid profile, expresses an optimised *Glycine max-hra* gene, which confers tolerance to acetolactate synthase-inhibiting herbicides and expresses the CP4 EPSPS protein which confers tolerance to glyphosate herbicides. For labelling purposes the requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation 1829/2003, the words 'with increased monounsaturated fat and reduced polyunsaturated fat' must appear after the name of the GMO on the label or, where appropriate, in the documents accompanying the products. The words 'not for cultivation' must also appear on the GMO-containing animal feed labels and in the accompanying documents. A method for detection (event specific real-time quantitative PCR) is available³⁵¹ as are Reference Materials ERM-BF426 (for DP-3Ø5423-1) and ERM-BF410 (for MON-Ø4Ø32-6 via the Joint Research Centre (JRC) of the European Commission.³⁵²

Commission Implementing Decision (EU) 2017/2449 of 21 December 2017³⁵³ authorised the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-68416-4. DAS-68416-4 soybean expresses the AAD-12 protein, which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides, and the PAT protein, which confers tolerance to glufosinate ammonium-based herbicides. Similar provisions to the above item prohibit cultivation and apply a detection method and reference materials.

Commission Implementing Decision (EU) 2017/2450 of 21 December 2017³⁵⁴ authorised the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6. Soybean DAS-44406-6 expresses the 2mEPSPS protein, which confers

³⁴⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1436450297142&uri=CELEX:02003R1829-20080410>

³⁴⁹ http://ec.europa.eu/food/plant/gmo_en

³⁵⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.346.01.0006.01.ENG&toc=OJ:L:2017:346:TOC

³⁵¹ <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>

³⁵² <https://ec.europa.eu/jrc/en/reference-materials/catalogue>

³⁵³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.346.01.0012.01.ENG&toc=OJ:L:2017:346:TOC

³⁵⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.346.01.0016.01.ENG&toc=OJ:L:2017:346:TOC

tolerance to glyphosate-based herbicides, the AAD-12 protein, which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides, and the PAT protein, which confers tolerance to glufosinate ammonium-based herbicides. Similar provisions to the above item prohibit cultivation and apply a detection method and reference materials.

Commission Implementing Decision (EU) 2017/2451 of 21 December 2017³⁵⁵ authorised the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 × A5547. Soybean FG72 × A5547-127, as described in the application, expresses the PAT protein, which confers tolerance to glufosinate ammonium-based herbicides, the 2mEPSPS protein, which confers tolerance to glyphosate-based herbicides and the HPPD W336 protein, which confers tolerance to isoxaflutole. Similar provisions to the above item prohibit cultivation and apply a detection method and reference materials.

Commission Implementing Decision (EU) 2017/2452 of 21 December 2017³⁵⁶ renewed the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 (DAS-Ø15Ø7-1). Maize 1507, as described in the application, expresses the Cry1F protein, derived from *Bacillus thuringiensis* subsp. *aizawai*, which confers resistance to the European corn borer (*Ostrinia nubilalis*) and certain other lepidopteran pests, and the PAT protein, derived from *Streptomyces viridochromogenes* strain Tü494, which confers tolerance to the herbicide glufosinate-ammonium. Similar provisions to the above item prohibit cultivation and apply a detection method and reference materials.

Commission Implementing Decision (EU) 2017/2453 of 21 December 2017³⁵⁷ authorised the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rapes MON 88302 × Ms8 × Rf3 (MON-883Ø2-9 × ACSBNØØ5-8 × ACS-BNØØ3-6), MON 88302 × Ms8 (MON-883Ø2-9 × ACSBNØØ5-8) and MON 88302 × Rf3 (MON-883Ø2-9 × ACS-BNØØ3-6). MON-883Ø2-9 oilseed rape expresses the CP4 EPSPS protein, which confers tolerance to glyphosate-based herbicides, ACS-BNØØ5-8 oilseed rape expresses the barnase protein and the PAT protein, which confers tolerance to glufosinate ammonium-based herbicides, ACS-BNØØ3-6 oilseed rape expresses the barstar protein and PAT protein, which confers tolerance to glufosinate ammonium-based herbicides. Similar provisions to the above item prohibit cultivation and apply a detection method and reference materials.

In a judgment of the European Court (Third Chamber) of 13 September 2017 (Case C-111/16) the court held that Member States cannot adopt interim emergency measures on GMOs solely on the basis of the 'precautionary principle', without appropriate conditions being satisfied (... likely to constitute a serious risk to human health, animal health or the environment). (Article 34 of Regulation No 1829/2003, read in conjunction with the precautionary principle as set out in Article 7 of Regulation No 178/2002).³⁵⁸

3.4.1 Cultivation of GMOs

Commission Directive 2015/412³⁵⁹ 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

³⁵⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.346.01.0020.01.ENG&toc=OJ:L:2017:346:TOC

³⁵⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.346.01.0025.01.ENG&toc=OJ:L:2017:346:TOC

³⁵⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.346.01.0031.01.ENG&toc=OJ:L:2017:346:TOC

³⁵⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.382.01.0016.01.ENG&toc=OJ:C:2017:382:TOC

³⁵⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.068.01.0001.01.ENG

their territory. This devolves responsibility in this matter to Member States. See our previous quarterly report³⁶⁰ for further details.

3.5 Cloned animals

Cloning involves the removal of the nucleus from a somatic cell (any body tissue) of an animal and its transfer into an enucleated egg (an egg cell that has had its own nucleus removed) of a donor female of the same species. This is then stimulated to generate an embryo for transfer into a surrogate mother. In April 2016 the Defra Farm Animal Genetic Resources Committee issued a statement on cloning of farm animals. EU legislation regards foods and food ingredients derived from clones as novel foods. However, the European Commission and both EFSA and the UK's FSA acknowledge that meat and milk from healthy clones and healthy offspring of clones is indistinguishable from, and as safe as that from, conventionally bred animals. The Defra Committee did not consider that there is any scientific justification for treating the products of the healthy offspring of clones, including semen and embryos, any differently from conventionally bred animals with regard to the production of food. The Committee noted that, in past trials, some cloned progeny have not developed normally, leading to significant welfare problems and premature death.³⁶¹

In September 2015 the European Parliament adopted at first reading a draft directive prohibiting cloning of farmed bovine, porcine, ovine, caprine or equine animals, based largely on animal welfare concerns. In September 2017 this was recast as a draft regulation.³⁶²

The Government Chemist last looked at the analytical science of cloned animals in 2012 when it was found that reproducible traits that would be discriminatory for healthy adult cloned animals could not be defined.³⁶³ This appears still to be the case.

3.6 Novel foods

Novel foods and novel food ingredients are regulated by Regulation (EC) No 258/97, replaced on 1 January 2018 by Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods.³⁶⁴ A Commission Q&A is available³⁶⁵ and a list of authorisations.³⁶⁶ The new regulation introduces a centralised authorisation procedure with EFSA conducting the scientific risk assessment and also introduces a notification procedure for traditional food from third countries. New EFSA guidance documents were finalised and adopted in November 2016.³⁶⁷

Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017³⁶⁸ lists EU novel foods authorised to date in accordance with Regulation 2015/2283 together with the conditions under which the novel food may be used, including maximum levels if applicable, any specific labelling requirements and any other requirements.

³⁶⁰ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2015>

³⁶¹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/524769/fangr-cloning-farm-animals-statement.pdf

³⁶² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.316.01.0278.01.ENG&toc=OJ:C:2017:316:TOC

³⁶³ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/332618/Cloned_animal_report.pdf

³⁶⁴ 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

³⁶⁵ http://europa.eu/rapid/press-release_MEMO-15-5875_en.htm

³⁶⁶ http://ec.europa.eu/food/safety/novel_food/authorisations/list_authorisations/index_en.htm

³⁶⁷ <https://www.efsa.europa.eu/en/press/news/161110>

³⁶⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.351.01.0072.01.ENG&toc=OJ:L:2017:351:TOC

See also Section 4.4 on food supplements for novel foods permitted only in supplements.

The Novel Foods (Wales) Regulations 2017 were made on 14 November 2017³⁶⁹, coming into force on 1 January 2018. The Regulations provide for the execution and enforcement in Wales of Regulation (EU) 2015/2283. The Regulations make food authorities responsible for their enforcement and provide that it is an offence for a person to fail to comply with Article 6(2) of the Regulation 2015/2283 by which only novel foods authorised by the Commission and included in the EU list of novel foods may be placed on the market. The foods must be in accordance with conditions of use and the labelling requirements set out in the list. Certain provisions of the Food Safety Act 1990 apply including enabling an authorised officer, if non-compliance is found, to give a notice that the food is not to be used for human consumption or is not to be removed except to some place specified in the notice, or to seize the food in order to have it dealt with by a justice of the peace; and enabling an improvement notice to be served requiring the person in charge of the food to comply with the provisions of the Novel Foods Regulation specified in Schedule 1 to these Regulations. The provisions, as applied, make the failure to comply with an improvement notice an offence. The Novel Foods and Novel Food Ingredients Regulations 1997 in relation to Wales, the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 in relation to Wales and the Food Enzymes (Wales) Regulations 2009 are revoked.

Similar provisions were made in the Novel Foods (Scotland) Regulations 2017³⁷⁰, and the Novel Foods Regulations (Northern Ireland) 2017³⁷¹ both also coming into force on 1 January 2018 with equivalent revocations.

Commission Implementing Decision (EU) 2017/2078 of 10 November 2017 authorised an extension of use of yeast beta-glucans (high molecular mass (100–200 kDa) polysaccharides), as a novel food ingredient under Regulation (EC) No 258/97. Yeast beta-glucans were first authorised by Commission Implementing Decision 2011/762/EU for use in certain foods and foodstuffs, including beverages, as well as in food supplements and in food for special medical purposes, and total diet replacement for weight control. The use categories have been extended, e.g. to biscuits, confectionery and jams, and the maximum levels of use have been increased. The designation in the labelling of the foodstuffs must be 'yeast (*Saccharomyces cerevisiae*) beta-glucans'.³⁷²

Commission Implementing Decision (EU) 2017/2201 of 27 November 2017 authorised the placing on the market of 2'-fucosyllactose, an oligosaccharide first found in milk in the 1950s³⁷³, produced with *Escherichia coli* strain BL21 as a novel food ingredient under Regulation (EC) No 258/97. Although 2'-fucosyllactose is produced by a genetically modified strain of *Escherichia coli* BL21 it falls outside the scope of Regulation 1829/2003 as the strain is used as a processing aid and the material derived from the genetically modified microorganism is not present in the novel food. The permitted use is in infant formulae and follow-on formulae at 1.2 g per litre of final ready for use product and the labelling designation is '2'-fucosyllactose'.

Pursuant to Regulation 258/97 Commission Implementing Decision (EU) 2017/2354 of 14 December 2017 authorised an extension of use of Chia seeds (*Salvia hispanica*) as a novel food ingredient in yoghurt with the maximum content of 1.3 g of whole Chia seeds per 100 g of yoghurt or 4.3 g of whole Chia seeds per 330 g of yoghurt (portion) with the designation 'Chia seeds

³⁶⁹ <http://www.legislation.gov.uk/wsi/2017/1103/contents/made>

³⁷⁰ <http://www.legislation.gov.uk/ssi/2017/415/contents/made>

³⁷¹ <http://www.legislation.gov.uk/nisr/2017/233/introduction/made>

³⁷² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.295.01.0077.01.ENG&toc=OJ:L:2017:295:TOC

³⁷³ <https://pubchem.ncbi.nlm.nih.gov/compound/170484#section=Top>

(*Salvia hispanica*)' (notified under document C(2017) 8470). Chia seeds were already authorised in bread products, baked products, breakfast cereals, fruit, nut and seed mixes, fruit juice and fruit juice blends and pre-packed Chia seeds as such.³⁷⁴

Commission Implementing Decision (EU) 2017/2355 of 14 December 2017 authorised the placing on the market of UV-treated mushrooms as a novel food (notified under document C(2017) 8474). The novelty is the mushrooms have been UV-treated to increase the level of vitamin D₂, Ergocalciferol, to 5-10 µg/100g fresh weight at the expiration of shelf life, and in any event ≤ 10 µg/100 g, with a designation of 'UV-treated mushrooms (*Agaricus bisporus*)'.³⁷⁵

Commission Implementing Decision (EU) 2017/2373 of 14 December 2017 authorised the placing on the market of hydroxytyrosol as a novel food ingredient (notified under document number C(2017) 8423).³⁷⁶ The synthetic form of hydroxytyrosol, found naturally in olives and olive oil, was assessed by EFSA as safe under the proposed uses and use levels.³⁷⁷ Some protective action has been demonstrated in preclinical studies against several diseases, especially cardiovascular and metabolic disorders.³⁷⁸ The permitted uses are in fish and vegetable oils, (except olive oils and olive pomace oils) to a maximum of 215 mg kg⁻¹ and spreadable fats as defined in Part VII of Annex VII of Regulation (EU) No 1308/2013 to a maximum of 175 mg kg⁻¹. The designation must be 'hydroxytyrosol' and the labelling of the food products containing it must include "This food product should not be consumed by children under the age of three years, pregnant women, and lactating women" and "This food product should not be used for cooking, baking or frying". LC-MS/MS methods of analysis appear to be available.

Commission Implementing Decision (EU) 2017/2375 of 15 December 2017 authorised the placing on the market of N-acetyl-D-neuraminic acid, NANA, also known as sialic acid, as a novel food ingredient (notified under document C(2017) 8431).³⁷⁹ The synthetic form of NANA found naturally in human milk as an endogenously produced monosaccharide, was assessed by EFSA as safe under the proposed uses and use levels, an ingredient in infant formula, follow-on formula, and foods for infants and young children as well as an ingredient in a variety of foods for the general population. The applicant also intends to market synthetic NANA in food supplements (as solid, liquid, syrup-type or chewable forms) for the general population with the intended maximum daily use levels of 300 mg.³⁸⁰ The designation for labelling is N-acetyl-D-neuraminic acid and food supplements containing N-acetyl-D-neuraminic acid shall be labelled in line with the presentation requirements applied under Regulation (EU) No 1169/2011 with a statement that the food supplement should not be given to infants, young children and children under 10 years of age where they consume breast milk or other foods with added N-acetyl-D-neuraminic acid within the same twenty four hour period. Methods of analysis include UPLC-FLD.

Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017³⁸¹ laid down administrative and scientific requirements concerning traditional foods from third countries. The

³⁷⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.336.01.0049.01.ENG&toc=OJ:L:2017:336:TOC

³⁷⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.336.01.0052.01.ENG&toc=OJ:L:2017:336:TOC

³⁷⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.337.01.0056.01.ENG&toc=OJ:L:2017:337:TOC

³⁷⁷ EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), Turck D., *et al.* (2017). Scientific opinion on safety of hydroxytyrosol as a novel food pursuant to Regulation (EC) No 258/97. *EFSA Journal* 2017, 15(3): 4728, 23pp. doi:10.2903/j.efsa.2017.4728. <http://www.efsa.europa.eu/en/efsajournal/pub/4728>

³⁷⁸ Bulotta S., Celano M., Lepore S. M., Montalcini T., Pujia A. and Russo D., (2014). Beneficial effects of the olive oil phenolic components oleuropein and hydroxytyrosol: focus on protection against cardiovascular and metabolic diseases. *Journal of translational medicine*, 12(1), p.219.

³⁷⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.337.01.0063.01.ENG&toc=OJ:L:2017:337:TOC

³⁸⁰ EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), Turck D., *et al.* (2017). Scientific Opinion on the safety of synthetic N-acetyl-d-neuraminic acid as a novel food pursuant to Regulation (EC) No 258/97. *EFSA Journal* 2017, 15(7):4918, 28 pp. <https://doi.org/10.2903/j.efsa.2017.4918>

³⁸¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.351.01.0055.01.ENG&toc=OJ:L:2017:351:TOC

scientific data to be provided in a notification or an application (Article 6) consist of a dossier from the third country to enable a history of safe use of the traditional food to be assessed, the procedure followed when gathering the data, the safety evaluation strategy justifying the inclusion or exclusion of specific studies or information and an overall conclusion on the safety of the proposed uses of the traditional food. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017³⁸² laid down administrative and scientific requirements for applications for novel food authorisation within the EU. The scientific data requirements (Article 5) to be provided in support include a dossier to enable a comprehensive risk assessment of the novel food. Where the application involves the use of engineered nanomaterials the applicant must provide detection and characterisation test methods.

The applicant must provide documentation on the procedure and strategy followed when gathering the dossier data, along with a description of the safety evaluation and toxicological testing strategies, and justify the inclusion or exclusion of specific studies or information. The applicant must also provide on request the raw data for the individual studies, published and unpublished, to support their application. Where it cannot be excluded that a novel food intended for a particular group of the population would be also consumed by other groups of the population the safety data provided shall also cover those groups. For each biological or toxicological study, the applicant shall clarify whether the test material conforms to the proposed or existing specification. Where the test material differs from that specification, the applicant shall demonstrate the relevance of those data to the novel food under consideration. Toxicological studies must be conducted in facilities which comply with the requirements of Directive 2004/10/EC or, if they are carried out outside the EU, follow the OECD Principles of Good Laboratory Practice. The applicant must provide evidence of compliance with those requirements and justify any deviation from the standard protocols. The applicant must propose an overall conclusion on the safety of the proposed uses of the novel food with an overall evaluation of potential risk to human health in the context of known or likely human exposure.

3.7 Consumer attitudes

The FSA publishes regular reports of surveys into information about the public's self-reported behaviours, attitudes and knowledge relating to food issues. The latest such report, published on 30 March 2017,³⁸³ found that broad consumer trends in relation to food remained largely consistent with previous waves of the survey. Consumers reported a number of practices that are in line with FSA recommendations on food safety in the home:

- More than eight out of ten respondents reported hand washing behaviours in line with recommended practices, saying they always washed their hands before starting to prepare or cook food (86%), and immediately after handling raw meat, poultry or fish (87%).
- The FSA recommends that the use by date is the best indicator of whether food is safe to eat, and this was cited as an indicator by 75% of respondents. While similar to the proportions in Wave 2 and Wave 3, this was higher than the proportion in Wave 1 (62%).

³⁸² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.351.01.0064.01.ENG&toc=OJ:L:2017:351:TOC
³⁸³ <https://www.food.gov.uk/news-updates/news/2017/16111/latest-food-and-you-survey-report-published>

The survey also flagged some areas where consumers report not following recommended best practice. The most common method reported to defrost meat or fish was leaving meat or fish at room temperature (58%), which is not recommended, (defrost in the fridge).

The findings also help to build a picture of consumers' eating out practices and highlight the importance of cleanliness and hygiene when people decide where to eat out. For example when shown a list of factors which might influence their decision on where to eat out, 72% reported that the cleanliness and hygiene of the establishment was important to them; overall a third (30%) of respondents who ate out considered this the most important factor.

New questions introduced in this wave provide some important insights to inform the FSA's future work including:

- Questions on allergy and intolerance which show that of those who reported an adverse reaction or avoided certain foods, the most common foods that people reported having an adverse reaction to were cows' milk and cows' milk products (22%), cereals containing gluten (13%) and molluscs, e.g. mussels, oysters (11%).

Similar surveys were conducted in Wales and Northern Ireland.

Key findings from Northern Ireland³⁸⁴ include:

- More than eight out of 10 respondents in Northern Ireland reported hand washing behaviours in line with recommended practices, saying they always washed their hands before starting to prepare or cook food (85%), and immediately after handling raw meat, poultry or fish (87%).
- When asked which methods they used to defrost meat or fish, the most common method was leaving meat or fish at room temperature (65%), which is not recommended.
- Respondents living in Northern Ireland, compared to those living in England, were more likely to agree that they recognised the Food Hygiene Rating Scheme (89% compared with 82%).

The findings also highlighted cooking, shopping and eating habits:

- Women in Northern Ireland were more likely than men to have all the responsibility for cooking or preparing food in the home (66% compared with 27%). And the proportion of women who reported having all or most of the responsibility for food shopping was more than twice the proportion of men (68% compared with 24%).
- When asked about the recommended number of calories average men and women should eat in a day, 38% mentioned 2,500 calories for men, and 41% mentioned 2,000 calories for women, both in line with recommendations.
- People in Northern Ireland were most likely to mention restaurants (58%), fast food restaurants (52%), and takeaway outlets (47%) as places where they would like to see more information about healthy eating options.

In Wales,³⁸⁵ hand washing was at a similar level to Northern Ireland with more than 8 out of 10 respondents reporting hand washing behaviours in line with recommended practices, saying they always washed their hands before starting to prepare or cook food (86%), and immediately after handling raw meat, poultry or fish (89%). The FSA recommends that the use by date is the best indicator of whether food is safe to eat, and this was cited as an indicator of whether food was safe to eat by 80% respondents in Wales. Welsh respondents (56%) also left meat or fish at room

³⁸⁴ <https://www.food.gov.uk/news-updates/news/2017/16162/latest-food-and-you-survey-report-published-for-northern-ireland>
³⁸⁵ <https://www.food.gov.uk/wales/news-updates/news/2017/16164/latest-food-and-you-survey-report-published-for-wales>

temperature to defrost which is not recommended. The findings also help to build a picture of Welsh consumer's eating out practices and highlight the importance of cleanliness and hygiene when people decide where to eat out. When shown a list of factors which might influence their decision on where to eat out, 71% of respondents in Wales reported that the cleanliness and hygiene of the establishment was important to them; overall a third (34%) of respondents who ate out considered this the most important factor. New questions introduced in this wave included questions on allergy and intolerance showing that of those in Wales who reported an adverse reaction or avoided certain foods, the most common foods that people reported having an adverse reaction to were cows' milk and cows' milk products (25%), cereals containing gluten (11%) and eggs (8%).

3.8 The Consumer Rights Act 2015

The Consumer Rights Act 2015, which in certain circumstances may be applicable to food, became law on 1 October 2015, replacing three major pieces of consumer legislation – the Sale of Goods Act, Unfair Terms in Consumer Contracts Regulations and the Supply of Goods and Services Act.^{386, 387}

A correction slip to the Consumer Rights Act 2015 was issued in October 2017.³⁸⁸

4 Health and nutrition

4.1 Nutrition and health claims

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods governs the use of these claims in the labelling, presentation and advertising of foods. It aims at enabling consumers to make healthier choices by protecting them from misleading information and ensuring a level playing field for food businesses to operate within the single market. Since its adoption in 2006, the implementation of the Regulation remains incomplete since nutrient profiles, that the Commission was requested to set by January 2009, have not been established and health claims on plants and their preparations used in foods are not yet fully regulated. The Commission's plan to carry out a REFIT evaluation of the EU legislation on nutrition and health claims was announced in its Better Regulation Communication of 19 May 2015. This REFIT evaluation aims at focusing on nutrient profiles and health claims on plants and their preparations added to foods. It also aims at considering the more general regulatory framework for the use of such substances in foods since it is closely related to the use of health claims. A route-map and progress are available.³⁸⁹

Guidance on nutrition labelling is available on the Commission website.³⁹⁰ Commission Regulation (EU) No 432/2012 established the list of permitted health claims and started to apply from 14 December 2012.³⁹¹ The EU Register of nutrition and health claims is also available³⁹² hence successive amendments to Regulation 432/2012 are not usually recorded here unless a change is made that requires further explanation.

³⁸⁶ <https://www.gov.uk/government/publications/consumer-rights-act-2015/consumer-rights-act-2015>

³⁸⁷ <http://www.which.co.uk/consumer-rights/regulation/consumer-rights-act>

³⁸⁸ http://www.legislation.gov.uk/ukpga/2015/15/pdfs/ukpgacs_20150015_en.pdf

³⁸⁹ http://ec.europa.eu/food/safety/labelling_nutrition/claims/refit/index_en.htm

³⁹⁰ http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm

³⁹¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012R0432>

³⁹² http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/index_en.htm

See also a 2017 publication that summarises current issues in nutrition and health claims.³⁹³

An example of the complexities of nutrition claims regulation is a case that occurred in August 2016 when Commission Regulation (EU) 2016/1413³⁹⁴ amended Regulation (EU) No 432/2012 in respect of two claims authorised for meal replacement for weight control. The conditions of use of those claims require that in order to bear them, the food should contain a maximum of 250 kcal per serving and comply with specifications laid down in Directive 96/8/EC. However Directive 96/8/EC has been replaced by Regulation 609/2013 (see Section 4.2) therefore, the references to Directive 96/8/EC needed to be replaced. Regulation 1169/2011 on the provision of food information to consumers (see Section 3.1) sets out nutrient reference values for vitamins and minerals that differ from some of those in Directive 96/8/EC.

The advice of EFSA was that this did not impact upon the substantiation of the two health claims and, further, there was no need to require that meal replacement for weight control provides at least 30 % of the nutrient reference values of fluoride, chromium, chloride and molybdenum per meal as laid down in Regulation (EU) No 1169/2011. Regulation 1169/2011 does not set a nutrient reference value for sodium. However, taking into account the intended use of meal replacement for weight control products, the requirement to provide 30 % of the sodium amount per meal as laid down in Directive 96/8/EC was maintained. A nutrient reference value for potassium is set at 2000 milligrams in Regulation 1169/2011. Directive 96/8/EC did not require for meal replacement for weight control to provide 30 % of the potassium value, but set a minimum amount at 500 milligram per meal and this value was maintained. The requirements set out in Directive 96/8/EC on fat, protein and amino acids were also maintained. Mandatory labelling particulars included in Directive 96/8/EC were maintained and a transitional period from 21 July 2016 until 14 September 2019 applies overall.

Regular bulletins are available from the Department of Health on EU legislation on nutrition and health claims.³⁹⁵

The assessment of some botanical claims is 'on hold'³⁹⁶ and an action was brought against the Commission for failure to act in that the Commission has unlawfully failed to initiate the assessment of health claims on botanical substances by EFSA. However this was dismissed by the court, see Order of the Court (Eighth Chamber) of 25 October 2016 – VSM Geneesmiddelen BV v European Commission, (Case C-637/15 P).³⁹⁷⁻³⁹⁹

Belgium has published a new decree, updating the “BELFRIT” project, a close cooperation between Belgium, France and Italy to harmonize the legislation on botanicals in food supplements. The number of plants authorized in food supplements in Belgium has increased significantly, from about 645 to more than 1000 plants. Consequently a considerable number of new conditions of use are now applicable. New maximum levels and mandatory warnings for about 250 plants will have to be taken into account when notifying food supplements. As a transitional measure, foodstuffs that do not comply with the provisions of the new decree, but

³⁹³ Walker, M. J. (2017), Health and nutrition claims – guidance, regulation and self-regulation, *Nutrition Bulletin*, 42: 69-79

³⁹⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1413>

³⁹⁵ <https://www.gov.uk/government/publications/nutritional-and-health-claims-legislation-bulletins-2015>

³⁹⁶ For further information see Walker, M. J. (2017), Health and nutrition claims – guidance, regulation and self-regulation. *Nutrition Bulletin*, 42, 69–79

³⁹⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.063.01.0007.02.ENG&toc=OJ:C:2017:063:TOC

³⁹⁸ <http://curia.europa.eu/juris/document/document.jsf?docid=174170&doclang=en>

³⁹⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62015CO0637>

conform with the provisions of the former decree, can still be placed on the market until 20 February 2019.⁴⁰⁰

4.1.1 Case law – ability to withhold authorisation despite EFSA favourable opinion

In an interesting case the European Court upheld the refusal of the Commission to authorise a series of health claims despite favourable EFSA opinions. The claims related to the normal metabolism of glucose and its support of normal physical activity. The Commission relied upon Regulation (EC) No 1924/2006 powers to withhold authorisation if health claims do not comply with general and specific requirements of the Regulation even in the face of a favourable scientific assessment by EFSA. The glucose health claims, it was held, would convey a conflicting and confusing message to consumers, because it would encourage consumption of sugars for which, on the basis of generally accepted scientific advice, national and international authorities advise consumers to reduce their intake. Therefore, such claims contravene point (a) of the second paragraph of Article 3 of the Regulation that claims should not be ambiguous or misleading. The applicant company brought an action seeking the annulment of the regulation which was refused by the General Court (Fifth Chamber) on 16 March 2016. The company appealed the decision which was again dismissed with costs against the appellant in July 2017.⁴⁰¹

4.1.2 Committee on Advertising Practice, CAP

On 9 December 2016 CAP announced new restrictions on advertising to children which will prevent the advertising of food and soft drinks that are high in fat, salt or sugar, HFSS, being targeted at children under 16. The rules apply across all non-broadcast media including on-line and social media. CAP have also amended existing content rules – these prohibit the use of promotions and licensed characters or celebrities in ads targeted through their content at under-12s – to allow non-HFSS advertising more freedom. The changes bring the CAP Code into line with the rules that have governed TV advertising since 2007.⁴⁰²

4.2 Food for infants and young children, medical purposes and weight control

Regulation (EU) No 609/2013, which came fully into effect from 20 July 2016, lays down general compositional and information requirements for the above categories of food, including infant formula and follow-on formula. The Commission adopted specific compositional and information requirements for infant formula and follow-on formula, taking into account the provisions of Directive 2006/141/EC. Infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first months of life until the introduction of appropriate complementary feeding. In order to safeguard the health of those infants, it is necessary to ensure that infant formula is the only product marketed as suitable for such use during that period. The essential composition of infant formula and follow-on formula must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data. Infant formula and follow-on formula are sophisticated products that are specially formulated for a vulnerable group of consumers. In order to ensure the safety and suitability of such products, detailed requirements are laid down on the composition of infant formula and follow-on formula, including requirements on energy value, macronutrient and micronutrient content. These requirements are based on an EFSA opinion on the essential composition of

⁴⁰⁰ <http://www.foodcomplianceinternational.com/blog/2017/2/15/new-belgian-belfrit-decree-on-botanicals-applicable>

⁴⁰¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.249.01.0010.02.ENG&toc=OJ:C:2017:249:TOC

⁴⁰² <https://www.cap.org.uk/News-reports/Media-Centre/2016/Insight-New-rules-ban-advertising-of-HFSS-food-and-drink-products-in-childrens-media.aspx#.WJr3eFJvhFo>

infant and follow-on formulae. Commission Delegated Regulation 2016/127⁴⁰³ supplements Regulation 609/2013 as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. Commission Delegated Regulation 2016/128⁴⁰⁴ supplements Regulation No 609/2013 as regards the specific compositional and information requirements for food for special medical purposes.

Domestic legislation to implement Regulation 609/2013 began in June 2016 with the Foods for Specific Groups (Scotland) Regulations 2016,190 coming into force on 20 July 2016.⁴⁰⁵ The Scottish instrument provides for enforcement by Scottish local authorities, offences and penalties and appropriate modification of certain provisions of the Food Safety Act 1990, amendment of the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 and revocation of subordinate legislation.

Domestic implementation of Regulation 609/2013 continued in July 2016 with the Food for Specific Groups (Information and Compositional Requirements) in England (and see below), Wales and Northern Ireland introducing an improvement notice, IN, enforcement regime in which failure to comply with an IN is a criminal offence. In the English⁴⁰⁶ and Welsh⁴⁰⁷ statutory instruments the IN regime sits alongside existing domestic criminal sanctions in the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997, the Medical Food (England) Regulations 2000, the Medical Food (Wales) Regulations 2000, the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003, the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Wales) Regulations 2004, the Infant Formula and Follow-on Formula (England) Regulations 2007, and their Welsh equivalent, the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009 and their Welsh equivalent.

In Northern Ireland⁴⁰⁸ enforcement at first instance is also by IN however the Notification of Marketing of Food for Particular Nutritional Uses Regulations (Northern Ireland) 2007 (S.R. 2007 No. 60), are revoked as are the Food for Particular Nutritional Uses (Miscellaneous Amendments) Regulations (Northern Ireland) 2010 (S.R. 2010 No. 33), and regulations 26 and 27 of the Infant Formula and Follow on Formula Regulations (Northern Ireland) 2007 (S.R. 2007 No. 506).

The Food for Specific Groups (Information and Compositional Requirements) (England) (Amendment) Regulations 2017 No.62, coming into force on 1 March 2017, corrected errors in SI 2016/688, and correctly applied a modified s.35 (Punishment of offences) of the Food Safety Act 1990.⁴⁰⁹

4.2.1 Total diet replacement for weight control

An attempt to introduce specific compositional and information requirements for total diet replacement for weight control under Regulation (EU) No 609/2013 was made with Commission

⁴⁰³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.025.01.0001.01.ENG&toc=OJ:L:2016:025:TOC

⁴⁰⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.025.01.0030.01.ENG&toc=OJ:L:2016:025:TOC

⁴⁰⁵ <http://www.legislation.gov.uk/ssi/2016/190/contents/made>

⁴⁰⁶ The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016
http://www.legislation.gov.uk/ukxi/2016/688/pdfs/ukxi_20160688_en.pdf

⁴⁰⁷ The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016
<http://www.assembly.wales/laid%20documents/sub-ld10709/sub-ld10709-e.pdf>

⁴⁰⁸ The Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016
<http://www.legislation.gov.uk/nisr/2016/251/made>

⁴⁰⁹ <http://www.legislation.gov.uk/ukxi/2017/62/contents/made>

Delegated Regulation (EU) 2017/1522 of 2 June 2017.⁴¹⁰ However this was declared null and void⁴¹¹ on 6 September 2017, to be replaced in October 2017 by Commission Delegated Regulation (EU) 2017/1798⁴¹² which provides that the product name under which food covered by Article 2(2)(h) of Regulation (EU) No 609/2013 is sold shall be ‘total diet replacement for weight control’. Regulation (EU) 2017/1798 sets out (a) compositional requirements, (b) requirements for labelling, presentation and advertising and (c) notification requirements for placing the product on the market. The provisions permit the voluntary addition to total diet replacement for weight control products of ingredients not covered by specific requirements, with particular attention, for example, to dietary fibre. As regards labelling Article 30(2) of Regulation (EU) No 1169/2011 (Food Information to Consumers) lists a limited number of nutrients that may be included on a voluntary basis in the nutrition declaration for food. The Annex to Regulation (EU) No 609/2013 lists a series of substances that may be added to total diet replacement for weight control products, some of which are not covered by Article 30(2) of Regulation (EU) No 1169/2011. Thus for legal clarity, Regulation (EU) 2017/1798 lays down explicitly that the nutrition declaration for total diet replacement for weight control products may include such substances. Compositional requirements include vitamins and minerals, and protein quality in terms of the amino acid profile.

4.3 Sugar

Sugar continues to be a topic of keen current interest. In October 2015 Public Health England, PHE, published⁴¹³ a review of a broad range of measures to reduce the nation’s excessive sugar consumption.

The Health (Miscellaneous Provision) Act (Northern Ireland) 2016: Chapter 26,⁴¹⁴ achieved Royal assent on 12 May 2016. This Act is to regulate the sale or use of nicotine products and tobacco, and to make other miscellaneous provisions but also includes provision in relation to sugar sweetened drinks. It requires the NI Department of Health, Social Services and Public Safety to carry out a study on a levy on sugar sweetened drinks within two years to determine:

- (a) a definition of sugar sweetened drinks;
- (b) which sugar sweetened drinks should be subject to a levy;
- (c) factors to be considered in determining and administering a levy;
- (d) the financial rate at which a levy may be set;
- (e) the anticipated health and economic impacts of the levy; and
- (f) the options for funding measures to address adverse health conditions associated with the consumption of sugary drinks derived from the levy revenue.

On 30 March 2017 PHE published new guidelines for the food industry demonstrating how it may be possible to remove 20% of the sugar in nine categories of food which contribute the most to children’s intakes.⁴¹⁵

PHE has engaged with all sectors of the food industry to reduce the amount of sugar in the foods that contribute most to children’s intakes by 20% by 2020, with a 5% reduction in the first year.⁴¹⁶ Industry response was positive.⁴¹⁷

⁴¹⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.230.01.0001.01.ENG&toc=OJ:L:2017:230:TOC

⁴¹¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.234.01.0007.01.ENG&toc=OJ:L:2017:234:TOC

⁴¹² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.259.01.0002.01.ENG&toc=OJ:L:2017:259:TOC

⁴¹³ <https://www.gov.uk/government/news/new-evidence-review-of-measures-to-reduce-sugar-consumption>

⁴¹⁴ http://www.legislation.gov.uk/nia/2016/26/pdfs/nia_20160026_en.pdf

⁴¹⁵ <https://publichealthmatters.blog.gov.uk/2017/03/30/expert-interview-new-guidelines-for-industry-on-the-sugar-reduction-programme/>

⁴¹⁶ <https://www.gov.uk/government/collections/sugar-reduction>

The government announced in the 2017 budget a proposal to introduce a soft drinks industry levy in April 2018. The new tax will be applied to soft drinks which contain added sugar, and have a total sugar content above certain thresholds. The government is introducing the levy in an effort to tackle obesity by reducing the consumption of drinks with added sugar, and to encourage manufacturers to reduce the sugar content of their products.^{418, 419}

Commission Implementing Regulation (EU) 2017/1344 of 18 July 2017⁴²⁰ amending Annex I to Council Regulation (EEC) No 2658/87 on the Common Customs Tariff and Commission Implementing Regulation (EU) 2017/1409 of 1 August 2017⁴²¹ amending Implementing Regulation (EU) No 75/2013 and Regulation (EC) No 951/2006 on import duties in the sugar sector give details of the calculation of the sucrose content of various products including isoglucose and certain syrups by HPLC or refractometry.

4.4 Food supplements

A useful summary by the Department of Health on legislation relating to the sale of food supplements is available.⁴²²

As part of the e-Library of Evidence for Nutrition Actions (eLENA)⁴²³ in August 2017 the WHO published two sets of guidelines on fortification of foods with micronutrients (vitamins and minerals):

- 'Use of multiple micronutrient powders for point-of-use fortification of foods consumed by pregnant women',⁴²⁴
- 'Use of Multiple Micronutrient Powders for Point-of-Use Fortification of Foods Consumed by Infants and Young Children Aged 6–23 Months and Children Aged 2–12 Years'.⁴²⁵

In a case referred from France the European Court (First Chamber) gave a ruling on 27 April 2017 that appears to block Member States from setting national legislation on vitamins and minerals in food supplements. The referring court, Tribunal de grande instance de Perpignan, asked three questions in relation to Directive 2002/46/EC and Community principles of free movement of goods and mutual recognition.⁴²⁶ Do the above measures (1) prevent national legislation precluding mutual recognition of products lawfully marketed in another Member State where their nutrient content exceeds limits set in the national legislation, and allow (2) national legislation to set nutrient limits based on (3) national scientific opinions that derive multiples of recommended daily allowances? The Court decided⁴²⁷ that Member States cannot enact national legislation based on national scientific opinions to prohibit, by limits on nutrients, sale of food supplements lawfully manufactured or marketed in another Member State. Any upper safe nutrient levels must be established by a comprehensive scientific assessment of the risks for public health, based not on general or hypothetical considerations, but on relevant scientific data.

⁴¹⁷ <https://www.fdf.org.uk/news.aspx?article=7778&newsindexpage=3>

⁴¹⁸ <https://www.gov.uk/government/publications/soft-drinks-industry-levy/soft-drinks-industry-levy>

⁴¹⁹ http://www.britishsoftdrinks.com/write/MediaUploads/Publications/The_Economic_Impact_of_the_Soft_Drinks_Levy.pdf

⁴²⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.186.01.0003.01.ENG&toc=OJ:L:2017:186:TOC

⁴²¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.201.01.0021.01.ENG&toc=OJ:L:2017:201:TOC

⁴²² <https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs> .

⁴²³ <http://www.who.int/elena/en/>

⁴²⁴ http://www.who.int/nutrition/publications/micronutrients/guidelines/mmpowders_pregnant_women/en/

⁴²⁵ http://www.who.int/elena/titles/guidance_summaries/micronutrientpowder_infants/en/

⁴²⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.090.01.0008.01.ENG&toc=OJ:C:2016:090:TOC

⁴²⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.202.01.0005.01.ENG&toc=OJ:C:2017:202:TOC

It is for the referring court to assess whether the method for the setting of those amounts at issue in the main proceedings complies with those requirements.

Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 governs the addition of vitamins and minerals and of certain other substances to foods and Annex II to Directive 2002/46/EC establishes the list of vitamin and mineral substances, which may be used in the manufacture of food supplements. Requests for the addition of organic silicon as a source of silicon, and separately, for calcium phosphoryl oligosaccharides (POs-Ca®) as a source of calcium, to the list set out in Annex II to Directive 2002/46/EC were processed by the Commission with EFSA being consulted. A favourable EFSA opinion ensued on organic silicon (monomethylsilanetriol; MMST) as a novel food ingredient for use as a source of silicon in food supplements and bioavailability of orthosilicic acid from the source. It follows from that opinion that the use of organic silicon (monomethylsilanetriol) in food supplements is not of a safety concern as a source of silicon, provided that certain conditions are respected. In EFSA's opinion the addition of calcium phosphoryl oligosaccharides (POs-Ca®) to food and its use in food supplements is not of a safety concern as a source of calcium, provided that certain conditions are respected. Thus Commission Regulation (EU) 2017/1203 of 5 July 2017 added both to Annex II to Directive 2002/46/EC.⁴²⁸

4.5 Novel foods in supplements

See the July – September 2017 edition⁴²⁹ (Sections 4.1.1 and 4.4.2) of this report for details of the authorisation of L-ergothioneine and prolyl oligopeptidase as novel foods in food supplements.

4.5.1 Taxifolin

Commission Implementing Decision (EU) 2017/2079 of 10 November 2017⁴³⁰ authorised the placing on the market of taxifolin-rich extract from the wood of Dahurian Larch (*Larix gmelinii* (Rupr.) Rupr) as a novel food ingredient under Regulation (EC) No 258/97. Taxifolin is a flavonoid also known as dihydroquercetin,⁴³¹ and was assessed by EFSA⁴³² and is said to exhibit varied bioactivity. The taxifolin-rich extract is permitted in food supplements as defined in Directive 2002/46/EC, *excluding* food supplements for infants, young children, children and adolescents younger than 14 years, to maximum use level of 100 mg per day.

4.5.2 *Calanus finmarchicus* oil

Commission Implementing Decision (EU) 2017/2353 of 14 December 2017 authorised the placing on the market of oil from *Calanus finmarchicus* as a novel food ingredient under Regulation 258/97 (notified under document C(2017) 8426). The crustacean (marine zooplankton) *C. finmarchicus* is harvested in the Norwegian Economic Zone including Jan Mayen island. A specification including 'wax esters > 85 %', minima for certain fatty acids and a maximum for peroxide value is given and the oil can be used in food supplements to a maximum consumption of 2.3 grams per day.⁴³³

⁴²⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.173.01.0009.01.ENG&toc=OJ:L:2017:173:TOC

⁴²⁹ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-july-to-september-2017>

⁴³⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.295.01.0081.01.ENG&toc=OJ:L:2017:295:TOC

⁴³¹ <https://pubchem.ncbi.nlm.nih.gov/compound/taxifolin#section=Top>

⁴³² <https://www.efsa.europa.eu/en/efsajournal/pub/4682>

⁴³³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.336.01.0045.01.ENG&toc=OJ:L:2017:336:TOC

4.6 Obesity and healthy eating

Obesity, as well as causing obvious physical changes, can lead to a number of serious and potentially life-threatening conditions, such as type 2 diabetes, coronary heart disease, some types of cancer, such as breast cancer and bowel cancer, and stroke. Obesity can also affect quality of life and lead to psychological problems, such as depression and low self-esteem.⁴³⁴ There are major implications for the National Health Service.

The Department of Health maintains a section of the government website dedicated to obesity and healthy eating policy, and best practice papers.⁴³⁵

In Wales the Public Health (Wales) Act 2017, Deddf Iechyd y Cyhoedd (Cymru) 2017, received Royal assent in July 2017 and includes provision for a national strategy on tackling obesity and other public health matters such as smoking.⁴³⁶

5 Regulation

A fundamental review of the basis of food and feed regulation is beyond the scope of this report however significant measures include the Food Safety Act 1990,⁴³⁷ the Food Standards Act 1999⁴³⁸ and the Official Feed and Food Controls (England) Regulations 2009 last amended, in England, by the Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015 that came into force on 6 April 2015, see Sections 5.4 and 6.1. European measures include Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law ... (etc),⁴³⁹ and Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 *on official controls and other official activities*^{440, 441} which replaced Regulation (EC) No 882/2004⁴⁴² in 2017. Background to this was given in a previous edition of this report.⁴⁴³ A fuller discussion of Regulation (EU) 2017/625 is at Section 1.4 of our April – June 2017 report.⁴⁴⁴

A dedicated section of the FSA website covers topics in enforcement and regulation. As well as information on food safety legislation, this section aims to provide enforcement officers with the tools they need to ensure that food safety and legal requirements are maintained and monitored in their area.⁴⁴⁵

⁴³⁴ <http://www.nhs.uk/Conditions/Obesity/Pages/Introduction.aspx>

⁴³⁵ <https://www.gov.uk/government/policies/obesity-and-healthy-eating>

⁴³⁶ <http://www.legislation.gov.uk/anaw/2017/2/part/1/enacted>

⁴³⁷ <http://www.legislation.gov.uk/ukpga/1990/16/contents> and see also

[The Food Safety Act 1990 \(Consequential Modifications\) \(Scotland\) Order 1990](#)

[The Food Safety Act 1990 \(Consequential Modifications\) \(No 2\) \(Great Britain\) Order 1990](#)

[The Food Safety Act 1990 \(Consequential Modifications\) \(England and Wales\) Order 1990](#)

[The Food Safety Act 1990 \(Commencement No. 1\) Order 1990](#)

[The Food Safety Act 1990 \(Commencement No. 2\) Order 1990](#)

[The Food Safety Act 1990 \(Commencement No. 2\) Order 1990](#)

⁴³⁸ <http://www.legislation.gov.uk/ukpga/1999/28/contents>

⁴³⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1488723013503&uri=CELEX:02002R0178-20140630>

⁴⁴⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.095.01.0001.01.ENG&toc=OJ:L:2017:095:TOC

⁴⁴¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1505320836050&uri=CELEX:02017R0625-20170407>

⁴⁴² <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1488722763430&uri=CELEX:02004R0882-20170216>

⁴⁴³ Walker M. J. (2017), Food and Feed Law: legislation review, January – March 2017, Section 5, pp 45 – 48,

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/617645/Foodfeedlaw_Jan-Mar_2017_v3.pdf

⁴⁴⁴ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2017>

⁴⁴⁵ <https://www.food.gov.uk/enforcement/>

5.1 International Developments

In the USA the FDA Food Safety Modernization Act (FSMA), the most sweeping reform of US food safety laws in more than 70 years, was signed into law by President Obama on 4 January 2011. In brief it aims to ensure the US food supply is safe by shifting the focus from responding to contamination to preventing it. The full text and guidance are available on the FDA website.⁴⁴⁶

The Intentional Adulteration Rule mandated by the FDA Food Safety Modernization Act (FSMA) requires food facilities, with some exceptions, to address hazards that may be introduced with the intention of causing wide-scale harm to public health. Further insights on protecting the food supply from intentional adulteration were given in December 2017 in an interview with FDA's Ryan Newkirk and Jon Woody.⁴⁴⁷

A useful review of food safety policy and regulation in the United States is available (dated 2015) from the European Commission.⁴⁴⁸

In Canada consultations continue on the proposed Safe Food for Canadians Regulations (SFCR) introduce modern food safety requirements for businesses that import food, or prepare food to be exported or sold across Canadian provinces.⁴⁴⁹

Pursuant to 2017/C 205/08⁴⁵⁰ on networking of organisations operating in fields within EFSA responsibilities an updated list of competent organisations is available⁴⁵¹ and includes, for the UK, Public Analyst laboratories, LGC, Fera, PHE and academic institutions.

5.2 Community Reference Laboratories

Regulation (EC) No 882/2004 lays down general rules for the performance of official controls to verify compliance with, *inter alia*, rules on food hygiene. In accordance with that Regulation, European Union reference laboratories ('EU reference laboratories') are responsible, in particular, for providing national reference laboratories with details of analytical methods and for the coordination of the application of such methods. The EU reference laboratories are listed in Annex VII to that Regulation (now replaced by Regulation 2017/625, see above).

Commission Regulation (EU) 2017/2460 of 30 October 2017⁴⁵² amended Annex VII to Regulation (EC) No 882/2004 to remove reference to the EU reference laboratory on milk and milk products since its work (e.g. on methods of analysis for on quality markers such as somatic cells counts) was complete.

See also Section 6.2, 'Feed Additives'.

⁴⁴⁶ <https://www.fda.gov/Food/GuidanceRegulation/FSMA/>

⁴⁴⁷ A Conversation with Ryan Newkirk and Jon Woody <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm587803.htm>

⁴⁴⁸ Directorate General For Internal Policies Policy Department A: Economic And Scientific Policy Food Safety Policy and Regulation In the United States,

[http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU\(2015\)536324_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf)

⁴⁴⁹ <http://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/regulatory-initiatives/sfca/consultation/eng/1426531180176/1426531265317>

⁴⁵⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.205.01.0057.01.ENG&toc=OJ:C:2017:205:TOC

⁴⁵¹ <http://www.efsa.europa.eu/sites/default/files/assets/art36listg.pdf>

⁴⁵² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.348.01.0034.01.ENG&toc=OJ:L:2017:348:TOC

5.3 Expert Scientific Committees

Following the March 2016 FSA triennial review of six FSA Scientific Advisory Committees⁴⁵³ the General Advisory Committee on Science (GACS) was replaced by the FSA Science Council chaired by Professor Sandy Thomas. The Science Council provides high-level, expert strategic insight, challenge and advice to the FSA's Chief Scientific Adviser and to the Board and executive of the FSA on the FSA's use of science to deliver FSA objectives. Its purpose is to help to ensure that the FSA identifies, sources, integrates and uses the best scientific evidence and expertise from all relevant disciplines to inform and evaluate its work. FSA defines science in a broad and inclusive way, including the natural, physical, social and economic, digital and data sciences.⁴⁵⁴

Other expert committees advising government on food and feed matters include:

- The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)⁴⁵⁵
- The Advisory Committee on the Microbiological Safety of Food (ACMSF)⁴⁵⁶
- The Advisory Committee on Animal Feedingstuffs (ACAF)⁴⁵⁷
- The Advisory Committee on Novel Foods and Processes (ACNFP),⁴⁵⁸ and
- The Social Science Research Committee (SSRC).⁴⁵⁹

The triennial review also recommended that the FSA should consult on moving the functions of the ACNFP and ACAF into a new committee, with a wider remit on innovation in the food chain. This was to be established by December 2017 but has not developed further to our knowledge. The review reinforced the importance of ensuring that the advisory committees continue to operate to the established high standards of independence, openness and transparency, including holding open meetings and publishing papers, minutes and reports, and having access to FSA officials and the Board.

5.4 Food Law Code of Practice

The Food Law statutory Codes of Practice for England and Wales and separately for Scotland and Northern Ireland are available on the FSA website.⁴⁶⁰ Food Law Practice Guidance that It is non statutory, complements the Code of Practice, and provides general advice on approach to enforcement of the law where its intention might be unclear.⁴⁶¹ The Scottish Food and Feed Law Guide was published in December 2016.⁴⁶²

A revised Food Law Code of Practice for England was issued on 30 March 2017.⁴⁶³

⁴⁵³ <https://www.food.gov.uk/news-updates/news/2016/15022/triennial-review-of-six-fsa-scientific-advisory-committees>

⁴⁵⁴ <https://science-council.food.gov.uk/>

⁴⁵⁵ <https://cot.food.gov.uk/>

⁴⁵⁶ <https://acmsf.food.gov.uk/>

⁴⁵⁷ <https://www.food.gov.uk/committee/acaf>

⁴⁵⁸ <https://acnfp.food.gov.uk/>

⁴⁵⁹ <https://ssrc.food.gov.uk/>

⁴⁶⁰ <https://www.food.gov.uk/enforcement/codes-of-practice/food-law-code-of-practice-2015>

⁴⁶¹ <https://www.food.gov.uk/sites/default/files/Food%20Law%20Practice%20Guidance%20October%202015%20-%20FINAL%20.pdf>

⁴⁶² <http://www.foodstandards.gov.scot/scottish-food-and-feed-law-guide>

⁴⁶³ <https://www.food.gov.uk/enforcement/codes-of-practice/food-law-code-of-practice>

5.5 Food law prosecutions database

In November 2015 the FSA announced⁴⁶⁴ the publication of a food law prosecutions database. The database⁴⁶⁵ 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.

5.6 Food law enforcement

5.6.1 Primary Authorities

Primary Authority is a scheme that allows businesses to form partnerships with local authorities in order to receive advice and guidance on regulatory matters. The Co-ordination of Regulatory Enforcement Regulations 2017⁴⁶⁶ made by the Department for Business, Energy & Industrial Strategy under powers in the Regulatory Enforcement and Sanctions Act 2008 create the framework under which Primary Authority operates. The regulations, brought into force on 1 October 2017, specify the regulators that may provide support to primary authorities⁴⁶⁷ and specify the functions in relation to which that support may be provided. The regulations describe what is regarded as enforcement action for the purposes of Primary Authority and the circumstances in which the enforcing authority does not have to notify the primary authority before it takes enforcement action. In such circumstances the enforcing authority must notify the primary authority as soon as it reasonably can after taking the enforcement action. There are procedures for references to the (BEIS) Secretary of State where there is dispute between the parties in relation to whether or not an enforcement action should go ahead.

For further information see the Regulatory Delivery section of the Department for Business, Energy & Industrial Strategy website.⁴⁶⁸

5.7 Food Standards Scotland

The Food (Scotland) Act 2015⁴⁶⁹ established the FSS and describes the structure and function of this new food body in Scotland which came into operation on 1 April 2015. See also Section 5.4, the Scottish Food and Feed Law Guide.

5.8 Import controls (contaminants, pesticides etc.)

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.

Commission Implementing Regulation (EU) 2017/2298 of 12 December 2017 amended Regulation (EC) No 669/2009. Highly perishable products or the product packaging may mean that sampling at the point of entry would inevitably result in a serious risk to food safety or in the product being damaged to an unacceptable extent. There is thus a derogation to allow sampling

⁴⁶⁴ <http://www.food.gov.uk/news-updates/news/2015/14644/food-standards-agency-publishes-food-law-prosecutions-database>

⁴⁶⁵ <http://www.food.gov.uk/enforcement/prosecutions>

⁴⁶⁶ <http://www.legislation.gov.uk/ukxi/2017/835/contents/made>

⁴⁶⁷ The Competition and Markets Authority, The Food Standards Agency, The Gambling Commission, The Health and Safety Executive and the (BEIS) Secretary of State

⁴⁶⁸ <https://www.gov.uk/government/organisations/regulatory-delivery>

⁴⁶⁹ http://www.legislation.gov.uk/asp/2015/1/pdfs/asp_20150001_en.pdf

at the place of destination. The amendment clarifies that the derogation may apply to imported products already listed in the Annex to Regulation 669/2009 as well as newly listed items. The amendments to the Annex include enhanced controls on pesticides in consignments of peppers (*Capsicum* spp.) from India and Pakistan. It is clarified that increased controls of pistachios from the United States (for aflatoxins) also includes roasted pistachios, and peppers (*Capsicum* spp.) from Thailand and Vietnam (for pesticides) includes frozen peppers. Regulation (EU) contains the current full list which (for chemical hazards) currently focuses on aflatoxins, ochratoxin A, pesticides residues, Sudan dyes, and sulphites.⁴⁷⁰

Commission Implementing Regulation (EU) 2016/874 of 1 June 2016 amended Implementing Regulation (EU) 2015/943 on emergency measures suspending imports of dried beans from Nigeria owing to residues of the pesticide dichlorvos. Concentrations exceeding the acute reference dose tentatively established by EFSA were found and the prohibition which was to be extended to 30 June 2019.⁴⁷¹ The corresponding entry in Regulation 669/2009 was deleted as unnecessary.

Implementing Regulation (EU) No 884/2014⁴⁷² remains in force and imposes special conditions on the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and was last amended by Regulation (EU) 2016/2106 that requires health certificates to accompany imports of spices from Ethiopia, groundnuts from Argentina, hazelnuts from Azerbaijan, dried figs and hazelnuts from Turkey and groundnuts from India.⁴⁷³

Commission Implementing Regulation (EU) 2015/949 approves the pre-export checks carried out on certain food or feed by certain third countries as regards the presence of certain mycotoxins. Such an approval of pre-export checks performed by the United States of America (US) authorities on aflatoxins in groundnuts was granted by the EU in 2008. The approval attests to the adequacy of pre-export controls so as to replace or reduce the documentary, identity and physical checks laid down in EU law. However, following an increase of non-compliance as regards the presence of aflatoxins in groundnuts from the US, groundnuts (peanuts) from the US were removed from the list of approved pre-export checks by Commission Implementing Regulation (EU) 2017/1269 of 13 July 2017 amending Implementing Regulation 2015/949.⁴⁷⁴

5.9 Local authority enforcement activity

On 21 November 2016 the FSA published official statistics on food law enforcement by local authorities across the UK for the year 2015/16. The figures are said to show an increase in a number of areas of local authority enforcement activity, and levels of hygiene compliance in food business, in spite of reported staffing reductions.⁴⁷⁵

On 18 September 2017 the FSA published official statistics on food law enforcement by local authorities for the year 2016/17. The information provided by local authorities and compiled by the FSA, gives a detailed breakdown of enforcement activity across the UK. These new data show an increase in food hygiene compliance in food establishments, continuing the trend of increases since 2014/15. However there was a decrease in the number of planned interventions

⁴⁷⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.329.01.0026.01.ENG&toc=OJ:L:2017:329:TOC#ntr15-L_2017329EN.01002802-E0015

⁴⁷¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.145.01.0018.01.ENG&toc=OJ:L:2016:145:TOC

⁴⁷² <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1499096567716&uri=CELEX:02014R0884-20161222>

⁴⁷³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.327.01.0044.01.ENG&toc=OJ:L:2016:327:TOC

⁴⁷⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.183.01.0009.01.ENG&toc=OJ:L:2017:183:TOC

⁴⁷⁵ <https://www.food.gov.uk/news-updates/news/2016/15747/fsa-publishes-local-authority-food-law-enforcement-information>

for food standards, which covers areas such as authenticity and food fraud. FSA intends to use the data, along with other intelligence, to identify and target underperforming local authorities and work with them to secure improvements.⁴⁷⁶

We remain open to including in this review any updates communicated by individual local authorities to the author. However see Section 5.5 for the food law prosecutions database which is based on local authority activity.

5.10 Multi-Annual National Control Plan

The FSA has published its annual report on progress towards implementation of the UK Multi-Annual National Control Plan (MANCP). The FSA considered that the report, which is based on data collected for 2016, shows that overall level of compliance in all sectors in the UK was satisfactory when assessed against expectations.⁴⁷⁷

5.11 National sampling priorities for food surveillance

The 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.⁴⁷⁸ The FSA invited⁴⁷⁹ recommendations for priorities for the 2016-17 National Coordinated Sampling Programme which were published in September 2016.⁴⁸⁰ On 29 November 2016 the FSA held a 'Food Surveillance Summit' as part of the development phase for a new food surveillance approach.⁴⁸¹ We are unaware of any further support going forward.

5.12 Online sales and surveillance

Online sales of food and general products is increasing and presents particular problems for regulators and enforcement authorities, mainly around the ephemeral nature of non-compliant operations, provision of information, lack of a physical premises to inspect, and jurisdictional issues. The Food Safety Authority of Ireland, FSAI, have issued what appears to be the first guidance setting out the information that must be provided to consumers by food businesses promoting or selling food online via websites or social media. It specifies what a business must do to comply with the law to ensure that consumers get the same information online, before making a purchase, as they would if they bought the product in a store. The legislation around labelling, advertising, health claims, nutrition claims and allergen declarations apply to foods sold online, as well as over the counter.⁴⁸² The European Commission have issued guidance on market surveillance of non-food products sold online that may, by analogy, assist those seeking to police online food sales.⁴⁸³

⁴⁷⁶ <https://www.food.gov.uk/news-updates/news/2017/16528/fsa-publishes-local-authority-food-law-enforcement-information>

⁴⁷⁷ <https://www.food.gov.uk/news-updates/news/2017/16505/2016-annual-report-on-uk-multi-annual-national-control-plan-published>

⁴⁷⁸ <https://www.food.gov.uk/enforcement/sampling/samplingandsurveillance>

⁴⁷⁹ <https://www.food.gov.uk/news-updates/help-shape-our-policies/priorities-for-the-2016-17-national-coordinated-sampling-programme>

⁴⁸⁰ <https://www.food.gov.uk/sites/default/files/food-sampling-guidance-2016-17.pdf>

⁴⁸¹ <https://www.food.gov.uk/news-updates/news/2016/15753/food-surveillance-summit-get-involved>

⁴⁸² https://www.fsai.ie/news_centre/press_releases/selling_online_guide_20072017.html

⁴⁸³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.250.01.0001.01.ENG&toc=OJ:C:2017:250:TOC

5.13 Regulators' development needs analysis, RDNA

The food section of the RDNA self-assessment tool has been updated to include the competency statements for authorised officers and lead food officers in the Food Law Code of Practice 2015.⁴⁸⁴ RDNA appears to be a useful mechanism of clarifying regulatory need and seems to be open to all stakeholders.⁴⁸⁵ There are links to the Guidance for Regulators Information Point (GRIP) portal that intended to help authorised officers and lead food officers in England meet their development needs both during and after their competency assessment processes.⁴⁸⁶

5.14 Standards in Public Life

The Committee on Standards in Public Life presented in September 2016 a report on how regulatory bodies in the United Kingdom uphold the Seven Principles of Public Life. The Committee was struck by the complexity and disparity of the regulatory landscape with a shared need to maintain integrity through independence – both from government and those they regulate – avoiding undue influence and ensuring the decisions they make are fair, well-reasoned and evidence-based. In light of the result of the June 2016 referendum in which the British people voted to leave the European Union (EU), the UK's regulatory landscape is likely to be substantially restructured in the coming years. The Committee made recommendations on Governance, Codes of Conduct, staff 'revolving door' issues, independence, transparency and external leadership.⁴⁸⁷

5.15 Official Food Chain Requirements and Methods of Analysis

Official methods or performance characteristics thereof are mentioned elsewhere in this report (e.g. 2.2.1 for contaminants and 2.7 for marine biotoxins) and proliferate throughout food law. This subsection is not intended to be comprehensive but will collate overarching food analytical methods as they arise. A source of food chain requirements and several diverse methods is Commission Regulation (EC) No 2074/2005⁴⁸⁸ of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 (hygiene rules for food of animal origin, (EC) No 854/2004 (official controls on products of animal origin intended for human consumption) and Regulation (EC) No 882/2004 (Official Controls). The requirements of Regulation 2074/2005 include methods and limit values for total volatile basic nitrogen (TVB-N) in fish, methods for marine biotoxins, and for raw milk and heat-treated milk, the applicable official controls for the inspection of meat, provisions on water retention agents in poultry and the calcium content of mechanically separated meat.

5.16 Corporate Reports

The Annual Report and Westminster Accounts 2016/17⁴⁸⁹ and the Annual Report and Consolidated Accounts 2016/17⁴⁹⁰ of the FSA were published in July 2017.

⁴⁸⁴ https://www.gov.uk/government/news/fresh-food?mc_cid=127fb196ca&mc_eid=f1b5809dbc

⁴⁸⁵ <http://rdna-tool.bis.gov.uk/>

⁴⁸⁶ <http://www.regulatorsdevelopment.info/grip/food>

⁴⁸⁷ CM 9327, Striking the balance, upholding the seven principles of public life in regulation:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/554817/Striking_the_Balance_web_-_v3_220916.pdf

⁴⁸⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1494594527755&uri=CELEX:02005R2074-20160603>

⁴⁸⁹ <https://www.food.gov.uk/sites/default/files/fsa-wstminster-accounts-2016-17.pdf>

⁴⁹⁰ <https://www.food.gov.uk/sites/default/files/fsa-consolidated-accounts-2016-17.pdf>

6 Feeding stuffs and fertilisers

6.1 Feeding stuffs

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 2015⁴⁹¹ (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:

- Commission Directive 82/475/EEC laying down the categories of feed materials which may be used for the purposes of labelling compound feeding stuffs 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 feeding stuffs 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.

⁴⁹¹ http://www.legislation.gov.uk/ukxi/2015/255/pdfs/ukxi_20150255_en.pdf

Similar regulations were made in Northern Ireland to make provision as to administration generally in relation to feed law, in particular so as to give effect to Regulation (EC) No. 882/2004. These were the Animal Feed (Composition, Marketing and Use) (Northern Ireland) Regulations 2016⁴⁹² (SR 4) amending:

- The Official Feed and Food Controls (Northern Ireland) Regulations 2009 (SR 427) and The Animal Feed (Hygiene, Sampling etc. and Enforcement) Regulations (Northern Ireland) 2016⁴⁹³ (SR 5) which supersede:
 - The Feed (Hygiene and Enforcement) Regulations (Northern Ireland) 2005 (SR.546);
 - The Feed (Specified Undesirable Substances) Regulations (Northern Ireland) 2006 (SR 471);
 - Regulation 46 and Schedule 7 of the Official Feed and Food Controls Regulations (Northern Ireland) 2009 (SR 427);
 - Regulations 4, 5, 6, 20, 21, and 22 and Schedule 1 of the Feed (Sampling and Analysis and Specified Undesirable Substances) Regulations (Northern Ireland) 2010 (SR 323);
 - The Feed (Hygiene and Enforcement) and the Animal Feed (Amendment) Regulations (Northern Ireland) 2013 (SR 294).

Commission Regulation (EU) 2017/2229 of 4 December 2017⁴⁹⁴ amended Annex I to Directive 2002/32/EC on undesirable substances in animal feed as regards maximum levels for lead, mercury, melamine and deoquinatate.

Commission Regulation (EU) 2017/2279 of 11 December 2017 amended certain Annexes to Regulation (EC) No 767/2009 on the placing on the market and use of feed. Annex II was amended to include specific expressions for feed for pets, including in English “pet food”. Annex IV Part A on tolerances for analytical constituents and feed additives in feed materials and compound feed is replaced. Annexes VI, and VII on labelling particulars for feed materials and compound feed for food-producing and non-food producing animals are replaced. Annex VIII on specific provisions for the labelling of feed which does not comply with safety and marketing requirements is amended with labelling provisions for contaminated materials only to be used as feed after detoxification in approved establishments, and former foodstuffs that need to be processed before they can be used as feed, must be labelled as: “former food, only to be used as feed material after ... (designation of the adequate process...)”.⁴⁹⁵

6.1.1 Mycotoxin recommended limits

Commission Recommendation (EU) 2016/1319⁴⁹⁶ of 29 July 2016 amended Recommendation 2006/576/EC as regards deoxynivalenol, zearalenone and ochratoxin A in pet food. Commission Recommendation 2006/576/EC establishes guidance values for deoxynivalenol, zearalenone, ochratoxin A, fumonisins B1+B2 and T-2 and HT-2 toxin in feed materials and compound feed. The current guideline level for deoxynivalenol in feed for dogs of 5 mg kg⁻¹ (from recent evidence including from EFSA) appears too high and is reduced to 2 mg kg⁻¹. Guideline levels for zearalenone and ochratoxin A in feed for cats and dogs are established at 0.2 mg kg⁻¹ and 0.01 mg kg⁻¹ respectively.

⁴⁹² http://www.legislation.gov.uk/nisr/2016/4/pdfs/nisr_20160004_en.pdf

⁴⁹³ http://www.legislation.gov.uk/nisr/2016/5/pdfs/nisr_20160005_en.pdf

⁴⁹⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.319.01.0006.01.ENG&toc=OJ:L:2017:319:TOC

⁴⁹⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.328.01.0003.01.ENG&toc=OJ:L:2017:328:TOC

⁴⁹⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016H1319>

6.1.2 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, the latest consolidated version⁴⁹⁷ is that of 23 April 2016 and includes updates in previous editions of this legislation review.

Commission Regulation (EU) 2017/771 of 3 May 2017⁴⁹⁸ amended Regulation (EC) No 152/2009 (see section 6.1) as regards the methods for the determination of the levels of dioxins and polychlorinated biphenyls. Regulation 152/2009 includes methods for the determination of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), dioxin-like polychlorinated biphenyls (PCBs) and non-dioxin-like PCBs in feed. On evidence from the EU reference laboratory for dioxins and PCBs in feed and food that analytical results for dioxins and PCBs in certain cases are not reliable when the performance criteria provided for in Part B of Annex V to Regulation (EC) No 152/2009 are not applied by laboratories performing the analysis of samples taken by feed business operators in accordance with Regulation (EC) No 183/2005, the application of the performance criteria for the analysis of such samples was made obligatory. Regulation 2017/771 deletes the decision limit in Commission Decision 2002/657/EC for the analysis of dioxins, furans and PCBs in feed in favour of the expanded uncertainty using a coverage factor of 2, giving a level of confidence of approximately 95 % and references guidance documents for the measurement uncertainty and for the estimation of the Limit of Detection (LOD) and Limit of Quantification (LOQ).⁴⁹⁹ Reporting requirements for physico-chemical methods used for screening are aligned with similar reporting requirements for bioanalytical screening methods and performance criteria are simplified and aligned generally. Along with some amended technical specifications, such as recoveries of isotope-labelled standards and other minor modifications, the whole Part B of Annex V to Regulation (EC) No 152/2009 is replaced.

6.1.3 Nickel in feed

EFSA requires further data on Ni in food of animal origin and accordingly Commission Recommendation (EU) 2016/1110 of 28 June 2016 asks Member States to monitor for the presence of nickel in feed.⁵⁰⁰

6.1.4 Starch content – analytical methods differ

Commission Implementing Regulation (EU) 2017/68 of 9 January 2017 amended Regulation (EC) No 121/2008 laying down the method of analysis for the determination of starch content in preparations of a kind used in animal feeding (CN code 2309). The classification of preparations of a kind used in animal feeding under the subheadings of heading 2309 of the Combined Nomenclature annexed to Council Regulation (EEC) No 2658/87 is determined on the basis of the product's starch content. For the purposes of that classification, Commission Regulation (EC) No 121/2008 (3) provides for use of an enzymatic analytical method for the determination of starch content in certain preparations. Where soya products are present in those preparations, their content of starch can be ascertained using the polarimetric method or the enzymatic analytical method. It has been found that substantially different results are obtained depending on the method used, and the polarimetric method has been found not to be suitable for determining the starch content of the preparations with soya products as it gives inaccurate results. Soya products are therefore added to the list of feed materials set out in Article 1 of Regulation (EC) No

⁴⁹⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498138333211&uri=CELEX:02005R0183-20160423>

⁴⁹⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.115.01.0022.01.ENG&toc=OJ:L:2017:115:TOC

⁴⁹⁹ http://ec.europa.eu/food/safety/animal-feed_en

⁵⁰⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1471533458929&uri=CELEX:32016H1110>

121/2008 in respect of which the starch content of the preparation is to be determined using the enzymatic analytical method in order to clarify which method the customs authorities are to use and thus ensure a uniform classification in the Member States.⁵⁰¹

6.2 Feed additives

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. A register of feed additives is available.⁵⁰² Guidance is available intended to help applicants in their preparation of technical dossiers for applications for authorisation.⁵⁰³

The Animal Feed (Scotland) Amendment Regulations 2017 No. 38,⁵⁰⁴ in force 23 March 2017, provide for the execution and enforcement of Commission Regulation (EU) 2015/327 amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions of use of additives consisting of preparations. These Regulations amend the Animal Feed (Scotland) Regulations 2010.

Commission Implementing Regulation (EU) 2017/1145 of 8 June 2017, pursuant to Article 10(5) of Regulation (EC) No 1831/2003, lists the repeal of obsolete provisions authorising feed additives which were entered in the Community Register of Feed Additives as existing products and for which no applications in accordance with Article 10(2) and (7) of Regulation (EC) No 1831/2003 were submitted before the deadline provided for in those provisions, or for which an application was submitted but subsequently withdrawn. The Annex to Regulation (EU) 2017/1145 lists over 200 such additives.⁵⁰⁵

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 2015/1761⁵⁰⁶ 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.

6.3 Fertilisers

Legislation on fertilisers is highly technical and treated here but briefly. The overarching European measure is Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003.⁵⁰⁷ This regulation is updated from time to time, including with references to validated analytical methods, see for example (non-exhaustively) Commission Regulation (EU) 2016/1618.⁵⁰⁸

⁵⁰¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.009.01.0004.01.ENG&toc=OJ:L:2017:009:TOC

⁵⁰² http://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register/index_en.htm

⁵⁰³ <http://www.efsa.europa.eu/en/efsajournal/pub/4473>

⁵⁰⁴ <http://www.legislation.gov.uk/ssi/2017/38/contents/made>

⁵⁰⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.166.01.0001.01.ENG&toc=OJ:L:2017:166:TOC

⁵⁰⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.257.01.0030.01.ENG

⁵⁰⁷ Latest consolidated version (Sept 2016) is at <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474134170231&uri=CELEX:02003R2003-20160101> however please consult EUR-Lex for the most up to date version <http://eur-lex.europa.eu/homepage.html>

⁵⁰⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1618>

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