Food and feed law:

Compendium of UK food and feed legislation with associated context and changes during January – March 2017

Government Chemist Programme Report

Department for Business, Energy & Industrial Strategy

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UK food and feed legislation
& changes during January – March 2017

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Introduction to 'Food and feed law' review series

This is the tenth in a series of quarterly reports that builds up a compendium of UK food and feed law and provides regular updates on developments in food and feed law and related scientific and regulatory issues. The reports form part of the Government Chemist project 'Support for the Government Chemist statutory function' in the 2014-2017 programme. The primary purpose is to track changes that relate to chemical measurement and the role of the Government Chemist. It also includes general issues in food and feed to ensure contextual awareness.

The reports in this series group the 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 include developments in Codex and other major trading blocs such as the US. International (*Codex Alimentarius*) and European measures are cited along with the implementing domestic legislation. English regulations are cited in the text; however for significant measures, where equivalent regulations have been made at the same time for Scotland, Wales and Northern Ireland, devolved references are given. Potentially temporary and local measures, such as prohibition legislation for shellfish harvesting areas, have not been recorded.

Please note – 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 January 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 that accompany each set of domestic regulations. Hyperlinks in the document were accessed and available at the date of this report. The reports are not indexed but the Table of Contents pp 4-6 is extensive.

Executive summary

This report updates the main text of our legislation review with developments in food and feed law and related scientific and regulatory issues for the period from January to March 2017. Changes from the previous version in the text in the main body of the report are indicated by a side bar in the left margin.

The two main overarching themes in the period January to March 2017 were exiting the EU and the modernisation of EU food and feed law.

The Supreme Court judgement on R (on the application of Miller and another) (Respondents) v Secretary of State for Exiting the European Union (Appellant) given on 24 January 2017 gives interesting background on the UK's relationship with the EU. The Supreme Court dismissed (two members dissenting) an appeal from the Secretary of State for Exiting the European Union against the decision of the English and Welsh Divisional Court upholding recourse to Parliament to bring about changes in domestic law in relation to exiting the EU. Devolution arguments relating to Northern Ireland, Scotland and Wales were also considered.

Consequently, the European Union (Notification of Withdrawal) Act 2017 was given Royal assent on 16 March 2017 and conferred power on the Prime Minister to notify, under Article 50 (2) of the Treaty on European Union, the United Kingdom's intention to withdraw from the EU.

The Prime Minister applied the powers conferred by the Act on 29 March, writing to European Council President Donald Tusk to notify him of the UK's intention to leave the EU.

A White paper published in February 2017 gave more details on the 'Great Repeal Bill' to remove the European Communities Act 1972 from the statute book and convert the 'acquis' – the body of existing EU law – into domestic law. This appears to mean that, wherever practical and appropriate, the same rules and laws will apply on the day after we leave the EU as they did before. This suggests food and feed law will remain initially unchanged. The White paper goes on to state that once the UK has left the EU, Parliament (and, where appropriate, the devolved legislatures) will decide which elements of that law to keep, amend or repeal.

Modernisation of European food and feed law took a significant step forward in February 2017 with the European Commission, Parliament and Council of Ministers reaching political agreement on a compromise text for a new all-encompassing Regulation on food controls. The general objective of the proposed Regulation is to simplify and streamline the existing legal framework of Regulation (EC) No 882/2004, encompassing almost all sectors of the agri-food chain in a unique set of rules applicable to official controls. The Regulation also aims to improve the efficiency of official controls performed by the Member States along the agri-food chain so as to allow for quick responses in crisis situations, while minimising the burden for operators.

Much of the proposed Regulation – which runs to 99 recitals and 167 Articles – will be familiar to those conversant with Regulation 882/2004. The proposal is dealt with more fully in the main text of our report however two aspects may be useful to highlight. One is that the proposed Regulation envisages recovery of costs for official controls from businesses, with non-compliant businesses paying more than compliant ones, and a series of administrative rules are elaborated in the draft. The other is that the draft Regulation includes in its Article 35 text that rehearses and extends the familiar provision of Article 11(5) of Regulation 882/2004 on supplementary expert opinion, now referred to as 'second expert opinion'. The writer's view is that the proposed Article 35 text is a useful extension of extant EU law in this area. The current UK Government Chemist arrangements for technical appeal (referee analysis) are likely to address the proposed

requirements. Moreover with a long history of implementation, and tailored to UK circumstances, present UK arrangements may prove to be more streamlined and hence more effective.

On a more detailed level new developments included further work on antimicrobial resistance, AMR, mineral oil hydrocarbons, legal highs, novel food, and methods for starch determination.

On 17 February 2017 the Codex Secretariat published the report of the working group on AMR, hosted by the UK and co-chaired by the USA and Australia, which met in London from 29 November to 2 December 2016. The report is available online as a working document of the 40th Codex Alimentarius Commission which will take place in Geneva in July 2017.

Mineral oil hydrocarbons (MOH), mineral oil aromatic hydrocarbons (MOAH) and mineral oil saturated hydrocarbons (MOSH) can have detrimental health effects on ingestion, with migration from food contact materials such as paper and board packaging suspected to contribute significantly to the total exposure. Thus a Commission Recommendation of January 2017 advised on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food. The European Union Reference Laboratory (EU-RL) for Food Contact Materials is mandated to develop guidance on methods of sampling and analysis.

A Council Implementing Decision of February 2017 signals control measures in some member state's national law for the 'illegal high' methyl 2-[[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA). This compound, a synthetic cannabinoid, has given rise to multiple reports of violence and aggression, poses a risk to driving as a consequence of its use and a total of 28 deaths and 25 acute intoxications have been reported. While the UK is not bound by the overarching legislation, and is not adopting the Decision, domestic law is expected to deal with the issue.

A new novel food was authorised, fermented soybean extract. EFSA have advised that this contains nattokinase which exhibits in vitro fibrinolytic activity and in vivo thrombolytic activity in animals when administered parenterally. It is therefore necessary to inform consumers about the need of medical supervision in cases when fermented soybean extract is consumed in combination with medication. These conditions are enforced by the authorising regulation.

In an interesting Regulation on the method of analysis for the determination of starch content in feed and classification in the Combined Nomenclature it was determined that of the two methods previously permitted, enzymatic and polarimetric, only the former is suitable (and now permitted as the method the customs authorities are to use) where soya products are present.

Contents

1 Cross-cutting issues

1.1 Exiting and new partnership with the European Union

In February 2017 a White paper[1] was published providing information on what the UK is seeking to achieve in negotiating an exit from, and new partnership with, the European Union. The White paper includes an intention to introduce the 'Great Repeal Bill' to remove the European Communities Act 1972 from the statute book and convert the 'acquis', the body of existing EU law, into domestic law. It is stated that this means that, wherever practical and appropriate, the same rules and laws will apply on the day after we leave the EU as they did before. This suggests food and feed law will remain initially unchanged. The White paper goes on to state that once the UK has left the EU, Parliament (and, where appropriate, the devolved legislatures) will decide which elements of that law to keep, amend or repeal.

The Supreme Court judgement[2] on R (on the application of Miller and another) (Respondents) v Secretary of State for Exiting the European Union (Appellant) given on 24 January 2017 gives interesting background on the UK's relationship with the EU. The Supreme Court dismissed (two members dissenting) an appeal from the Secretary of State for Exiting the European Union against the decision of the English and Welsh Divisional Court upholding recourse to Parliament to bring about changes in domestic law in relation to exiting the EU. Devolution arguments relating to Northern Ireland, Scotland and Wales were also considered.

Consequently, the European Union (Notification of Withdrawal) Act 2017[3] was given Royal assent on 16 March 2017 and conferred power on the Prime Minister to notify, under Article 50 (2) of the Treaty on European Union, the United Kingdom's intention to withdraw from the EU. The Act contains only two sections hence may be reproduced here for interest.

> **1 Power to notify withdrawal from the EU**
> (1) The Prime Minister may notify, under Article 50(2) of the Treaty on European Union, the United Kingdom's intention to withdraw from the EU.
> (2) This section has effect despite any provision made by or under the European Communities Act 1972 or any other enactment.
> **2 Short title**
> This Act may be cited as the European Union (Notification of Withdrawal) Act 2017.

A short explanatory note is also available in conjunction with the published Act.

The Prime Minister applied the powers conferred by the Act on 29 March, writing to European Council President Donald Tusk to notify him of the UK's intention to leave the EU.[4] The letter also suggested the principles that might underpin negotiations:

> i. We should engage with one another constructively and respectfully, in a spirit of sincere cooperation.
> ii. We should always put our citizens first.
> iii. We should work towards securing a comprehensive agreement.

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1 https://www.gov.uk/government/publications/the-united-kingdoms-exit-from-and-new-partnership-with-the-european-union-white-paper
2 https://www.supremecourt.uk/cases/docs/uksc-2016-0196-judgment.pdf
3 http://www.legislation.gov.uk/ukpga/2017/9/contents/enacted
4 https://www.gov.uk/government/publications/prime-ministers-letter-to-donald-tusk-triggering-article-50

iv. We should work together to minimise disruption and give as much certainty as possible.
v. In particular we must pay attention to the UK's unique relationship with the Republic of Ireland and the importance of the peace process in Northern Ireland.
vi. We should begin technical talks on detailed policy areas as soon as possible, but we should prioritise the biggest challenges.
vii. We should continue to work together to advance and protect our shared European values.

On 31 March 2017 the Department for Exiting the European Union issued a White Paper, 'Legislating for the United Kingdom's withdrawal from the European Union'[5]. This confirms the conversion of existing EU law into domestic legislation and clarifies that any question as to the meaning of EU-derived law will be determined in the UK courts by reference to the Court of Justice of the European Union case law as it exists on the day the UK leaves the EU.

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.[6] A 2016 publication, 'Understanding Codex'[7] is a valuable guide to its operation. The core function of Codex is the development of international standards and the 39th Commission adopted 39 new and revised texts in 2016.

1.3 Food regulation

On 17 October 2016 the Food Standards Agency, FSA, issued a statement on future food regulation. Restating the FSA strategic priorities "to make sure that people have safe food, food they can trust, and that it is what it says it is" FSA confirmed a need to change the way food is regulated to achieve these aims. This stems from business innovation outstripping the way regulation has always been done. FSA believes it needs to keep pace with this and wants businesses to take proper responsibility for food safety and local authority resources to be properly used. FSA is proposing a model that continues to use inspections and visits alongside the information gained from business's data and accredited third party audits. FSA undertook a three month trial to compare the data held by certain food businesses with the data that local authorities collect from inspections to see if it can be used to provide information as part of setting the standard to create a new, more comprehensive and transparent system of business assurance.[8] The study reports[9] showed that industry data could potentially be used by enforcement officers to assess the compliance of food businesses. However, further work is necessary to establish how private sector audit data could be used to provide assurance that businesses are complying with food law. FSA has published information including a series of newsletters on 'regulating our future'.[10]

The FSA Board discussed 'regulating our future' at its open meeting on 15 March 2017 with an update from FSA Director Nina Purcell. Commenting during the board debate, FSA Chairman

5 https://www.gov.uk/government/publications/the-great-repeal-bill-white-paper/legislating-for-the-united-kingdoms-withdrawal-from-the-european-union
6 http://www.fao.org/fao-who-codexalimentarius/codex-home/en/
7 http://www.fao.org/3/a-i5667e.pdf
8 https://www.food.gov.uk/news-updates/news/2016/15592/fsa-statement-on-future-food-regulations
9 https://www.food.gov.uk/news-updates/news/2017/16046/regulating-our-future-assurance-studies-published
10 https://www.food.gov.uk/enforcement/regulation/regulating-our-future

Heather Hancock took the opportunity to rebut any suggestion that the FSA was moving towards a model of self-regulation for UK food businesses. The Board emphasised again that the FSA remained committed to delivering a fundamentally better system that offered agility and confidence as food risks and food businesses changed.[11]

1.4 Antimicrobial resistance, AMR

On 25 November 2016 the FSA published a systematic review of the available evidence on antimicrobial resistance, AMR, in food. The review looked at research on the presence of AMR in bacteria in a number of different foods sold at retail. The research has 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 AMR review was produced by the Royal Veterinary College, on behalf of the FSA, and looked at the areas where consumers are more likely to be exposed to AMR in bacteria from the food chain. Researchers examined published evidence between 1999 and 2016 for pork and poultry meat, dairy products, seafood and fresh produce sold in shops. The research was released ahead of a *Codex Alimentarius* working group on AMR held in London on 29 November to 2 December 2016.[12] The working group was organised by the FSA and chaired by the UK, USA and Australia. It is the first step in this new area of work, and will set terms of reference for the intergovernmental task force that will follow.[13]

On 17 February 2017 the Codex Secretariat published[14] 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 will take place in Geneva in July 2017.

The working group, attended by 110 people consisting of: 33 Member Countries, 1 Member Organisation, 13 Observers Organisations, FAO and WHO and the Codex Secretariat, reviewed and revised the following project documents:

- Proposal for new work on the revision of the Code of Practice to Minimise and contain Antimicrobial Resistance (CAC/RCP 61-2005); and
- Proposal for new work on the Guidance on Integrated Surveillance of Antimicrobial Resistance.

Consensus was achieved on the revised project documents (Appendices 1 and 2 in the report), and the revised Terms of Reference for the Provision of Scientific Advice on Antimicrobial Resistance, (Appendix 3 in the report).

An electronic working group was deemed an appropriate mechanism for the elaboration of text in each of the two areas of new work.

Codex also reported in February 2017 the 10th International Feed Regulators Meeting when feed industry representatives and government officials from 35 countries met to discuss key issues including Feed Safety Risk Management Strategies and the role of animal nutrition and feeding to minimise antimicrobial resistance (AMR). The meeting was also informed on the activities of the FAO led Multi-stakeholder Partnership for Capacity Development for Feed Safety.[15]

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[11] https://www.food.gov.uk/news-updates/news/2017/16063/summary-of-discussions-at-fsa-board-meeting-15-march-2017
[12] http://www.fao.org/fao-who-codexalimentarius/roster/detail/en/c/456452/
[13] https://www.food.gov.uk/news-updates/news/2016/15746/fsa-publishes-review-of-antimicrobial-resistance-evidence
[14] http://www.fao.org/fao-who-codexalimentarius/roster/detail/en/c/471647/
[15] http://www.fao.org/fao-who-codexalimentarius/roster/detail/en/c/470458/

FAO has produced a useful report on the 'drivers, dynamics and epidemiology of antimicrobial resistance in animal production'.[16]

1.5 Emerging risks

The Emerging Risks Exchange Network, EREN, has been referred to in previous reports[17] and regularly updates outline emerging risks in brief meeting reports[18]. At the meeting of EREN in April 2016 the following chemical risks were discussed:

- Antimicrobial resistance
- Potential risks associated to uses of seaweed
- The circular economy – pollution from waste to fertiliser to the food chain
- Pyrrolizidine alkaloids in different types of teas on the Croatian market
- Risks associated with the use of green tea extracts in food supplements
- Recycled electric and electronic plastics
- Cyanobacteria toxins in food
- Tetrodotoxin, TTX
- Risk profile of insects as food and feed
- Cyanogenic glycosides in apricot kernels and products derived from apricot kernels.

One of the European Food Standards Agency's (EFSA) key aims is to develop, in collaboration with Member States, an assessment of "prioritised activities and initiatives which are likely to have the greatest impact in strengthening risk assessment and risk monitoring". To support this, EFSA commissioned a 'Delphi'[19] survey of risk assessment experts throughout Europe.[20] Analysis of the initial results yielded consensus with 28 topics taken forward for further discussion with the experts. The 28 topics were as follows and the top-rated **highlighted in bold**:

Generic:

- Methods and systems for identifying emerging (food) risks (e.g. new food-borne diseases)
- **Development of standard risk-benefit assessment methods**
- **Common data collection/surveillance scheme across Europe**
- Multiple contaminant impacts on the risk profile of foods
- Risks/benefits of botanicals/herbals in food supplements
- Allergenicity/food allergens in general (risk assessment and management)
- **Aggregated exposure (as per cocktail effects, but including environmental as well as food exposures).**

Chemical:

- Harmonisation of methods for risk assessment of chemical contaminants
- Cumulative exposure assessment (e.g. for pesticide residues/PAHs)
- Infant and baby food
- Emerging contaminants.

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

[17] https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-january-to-march-2016

[18] https://www.efsa.europa.eu/en/topics/topic/emergingrisks

[19] The Delphi technique is a structured process that uses a series of questionnaires or 'rounds' to gather information. Rounds are held until group consensus is reached, see for example Boulkedid, R., Abdoul, H., Loustau, M., Sibony, O. and Alberti, C. (2011) Using and reporting the Delphi method for selecting healthcare quality indicators: a systematic review, *PloS one*, 6(6): p.e20476; and Powell, C. (2003) The Delphi technique: myths and realities. *J Adv. Nurs.,* 41: 376–382

[20] Rowe, G. and Bolger, F. (2016) Final report on 'the identification of food safety priorities using the Delphi technique' http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1007e.pdf

Microbiological:

- Systems for monitoring and characterising microbes isolated from food, environment and human illness cases
- Improve the use of genetic data (e.g. from whole genome sequencing) for risk assessment of microbiological contaminants
- **Antimicrobial/antibiotic resistance**
- Microbial food pathogens (in general)
- Food-borne viruses (in general) (e.g. Hepatitis A and Norovirus in fruit and vegetables)
- Campylobacter (e.g. in poultry and ready to eat foods)
- **Zoonoses (in general, including bio-hazards, MRSA etc.).**

Environmental:

- Improving information on the occurrence and spread of harmful organisms at the level of individual EU countries
- Ribonucleic acid interference (RNAi) applied to food producing organisms as pesticide, veterinary medicine, or newly expressed trait in genetically modified crops
- Better understanding of biological organisms and plant substances used in crop protection (so reducing the need for chemicals e.g. pesticides)
- The impact of chemicals on the ecosystem (release of chemicals to the environment)
- **Presence/detection of environmental contaminants (e.g. from agricultural, industrial or household sources) in food**
- Cocktail effects (the health risk assessment of chemical mixtures, e.g. food additives).

Nutrition:

- Indirect effects on human health due to modified agricultural practices (e.g. via reduction of pesticide use, changed content of mycotoxins, etc.)
- Developing standard biomarkers of intake and/or exposure to contaminants
- Food supplements risk/benefits
- Determination of allergen thresholds (clinical studies), in conjunction with immunochemical measurements of allergens in foods
- Development of standard risk-benefit assessment methods (of foods).

A meeting of EREN took place on 14 November 2016[21] at which the following chemical topics were considered.

- Food supplements in general
- Use of hesperidin and diosmin in food supplements
    - Polyphenols – such as these compounds – are used in in food supplements for their biological and antioxidant activity, and the auxiliary treatment of diseases, such as hypercholesterolemia, high blood pressure, haemorrhoids, phlebitis, and chronic venous insufficiency. An HPLC method is available.[22]
- Use of piperine in food supplements
    - Piperine, an alkaloidal constituent of pepper, has been found to enhance the blood levels of some drugs by altering absorption or metabolism.[23]

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[21] https://www.efsa.europa.eu/en/events/event/161114 dated 23.12.16

[22] Šatínský, D., Jägerová, K., Havlíková, L. and Solich, P. (2013) A new and fast HPLC method for determination of rutin, troxerutin, diosmin and hesperidin in food supplements using fused-core column technology. *Food Anal. Methods*, *6*(5), 1353-1360

[23] Velpandian, T., Jasuja, R., Bhardwaj, R.K., Jaiswal, J. and Gupta, S.K. (2001) Piperine in food: interference in the pharmacokinetics of phenytoin. *Eor. J Drug Metab. Ph.*, *26*(4), 241-247

- Risks associated with the use of aloe plant extracts in food or as food
    - Opinion is divided between safety for human consumption and the possibility of aloin contamination reported as DNA damaging.[24]
- Antimicrobials in honeybees
- TTX (tetrodotoxin) in mussels and oysters
    - TTX, a neurotoxin, occurs naturally in (sub)tropical seas. Highly likely to be produced by a bacterium, it is best known from its occurrence in pufferfish.
- Risk assessment on hay as a food or food ingredient
- 3D food printing[25]
- High content screening[26] tools e.g. 'KNIME',[27] collected emerging issues and price trend analysis.

1.5.1 Food Crime

The concept of 'food crime' was highlighted by the Elliott Review which led to the establishment of the FSA's National Food Crime Unit[28], NFCU.

Food Standards Scotland independently established a Scottish Food Crime and Incidents Unit (SFCIU).[29]

On 28 November 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.[30] This followed the review of the NFCU published on 10 November 2016. The review, carried out by FSA under the oversight of an independent steering group, recommended NFCU should be given additional powers and resources to boost its ability to tackle food crime and protect consumers.[31]

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.[32] The report as a whole provides good background context for a topic in which molecular biology has a significant role to play.

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.[33]

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

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[24] Ahlawat, K.S. and Khatkar, B.S. (2011) Processing, food applications and safety of aloe vera products: a review. *J Food Sci. Tech.*, *48*(5), 525-533
[25] See for example https://3dfoodprintingconference.com/
[26] Zanella, F., Lorens, J.B. and Link, W. (2010) High content screening: seeing is believing. *Trends Biotechnol.*, *28*(5), 237-245
[27] KNIME: Konstanz Information Miner, see, for example Berthold, M.R., Cebron, N., Dill, F., Gabriel, T.R., Kötter, T., Meinl, T., Ohl, P., Thiel, K. and Wiswedel, B. (2009) KNIME-the Konstanz information miner: version 2.0 and beyond. *AcM SIGKDD explorations Newsletter*, *11*(1), 26-31.
[28] https://www.food.gov.uk/enforcement/the-national-food-crime-unit
[29] http://www.foodstandards.gov.scot/food-crime
[30] https://www.food.gov.uk/news-updates/news/2016/15226/food-crime-confidential-launch
[31] https://www.food.gov.uk/news-updates/news/2016/15679/nfcu-review-published
[32] https://www.unodc.org/documents/data-and-analysis/wildlife/World_Wildlife_Crime_Report_2016_final.pdf
[33] https://www.food.gov.uk/news-updates/news/2016/15642/nfcu-launches-industry-guide

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.[34]

In late March 2016 the Food Standards Agency (FSA) published[35] 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. There is some overlap with the above EFSA data, in relation to meat speciation issues.

1.5.2 Incidents

In June 2016 the FSA published[36] its annual report of 2015 food incidents. It showed that in 2015, the FSA and Food Standards Scotland, 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.

In October 2016 the FSA published the continuing series of within year lists of incidents.[37] 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.

1.6 Information management

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.

A United Nations publication outlines a framework for integrated agrifood 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 agrifood 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 agrifood information systems for trade facilitation are provided, including a recommendation to develop a Single Window for Agrifood Trade (SWAT). This publication is aimed mainly at government officials involved in overseeing and making policies related to agrifood trade. It is also relevant to the private sector (both existing and potential traders), associations and any agrifood supply-chain stakeholders interested in making agrifood trade both safer and more efficient. This policy guide builds on the series of technical and legal

[34] https://www.campdenbri.co.uk/pr/food-fraud.php
[35] 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
[36] http://www.food.gov.uk/news-updates/news/2016/15190/fsa-annual-report-of-incidents-2015-published
[37] https://www.food.gov.uk/news-updates/news/2016/15641/fsa-publishes-list-of-incidents-for-july-to-september-2016

guides produced by UNNExT to facilitate paperless trade implementation.[38] Previous guides are also available.[39]

1.7 Global data

Two useful compendia of data were published in late 2016: the World Bank 'Little green data book 2016'[40] and the United Nations 'World statistics pocketbook 2016'.[41] 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.[42]

1.8 Machinery of Government

An Order in Council[43] 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).

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.[44-47] A significant

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[38] Information management in agrifood chains: towards an integrated paperless framework for agrifood trade facilitation http://unnext.unescap.org/pub/agriguide15.pdf

[39] http://unnext.unescap.org

[40] http://data.worldbank.org/products/data-books/little-green-data-book

[41] http://unstats.un.org/unsd/publications/pocketbook

[42] Common catalogue of varieties of agricultural plant species — 35th complete edition

[43] 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

[44] 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

[45] 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

[46] 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

[47] 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

development in the area was the conviction of Mohammed Zaman at Teesside Crown Court for manslaughter following the death of a peanut allergic customer who had a reaction to a curry.[48]

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.[49, 50]

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;[51] national provisions will allow enforcement at UK level.[52]

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,[53] 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.[54] 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);

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48 http://www.bbc.co.uk/news/uk-england-36360111
49 https://www.fdf.org.uk/news.aspx?article=7539
50 https://www.fdf.org.uk/herbs-spices-guidance.aspx
51 http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1471529878473&uri=CELEX:32014R0828
52 https://www.coeliac.org.uk/about-us/news/changes-to-european-legislation-on-gluten-free-labelling/
53 http://www.legislation.gov.uk/ssi/2016/191/contents/made
54 https://www.food.gov.uk/sites/default/files/food-information-regulations-ni-2016.pdf

- In Wales by the Food Information (Wales) (Amendment) Regulations 2016[55] 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.[56]

The Food Standards Agency 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,[57] (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%).

2.2 Contaminants

Regulation (EC) No 1881/2006 remains the primary European legislation, the latest consolidated version of which was published in April 2016.[58] This is a measure that is frequently updated and almost always features in our quarterly updates. A useful summary of contaminant information is available on the European Commission website.[59]

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.[60]

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

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[55] http://www.legislation.gov.uk/wsi/2016/664/made
[56] https://www.food.gov.uk/news-updates/news/2016/15656/fifth-csa-report-launched
[57] https://www.food.gov.uk/news-updates/news/2017/16111/latest-food-and-you-survey-report-published
[58] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1466704439817&uri=CELEX:02006R1881-20160401
[59] http://ec.europa.eu/food/safety/chemical_safety/contaminants/index_en.htm
[60] 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

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.[61]

2.2.3 Dioxins and polychlorinated biphenyls (PCBs)

Regulation 1881/2006 establishes, with certain derogations, maximum levels for dioxins, for the sum of dioxins and dioxin-like PCBs and for non-dioxin-like PCBs in fish and fishery products.

Please refer to previous editions of this review for further details.[62]

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 even cooking, examples include:

- Acrylamide
- Apricot kernels – cyanide
- Glycerol based process contaminants (MCPD and GE)
- Endocrine disruptors
- Nickel

Updates on the above are in previous editions of this review[63] 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)[64] to help people understand how to minimise exposure to acrylamide when cooking at home.

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

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61 Corrigendum to Commission Regulation (EU) No 519/2014 of 16 May 2014 amending Regulation (EC) No 401/2006 as regards methods of sampling of large lots, spices and food supplements, performance criteria for T-2, HT-2 toxin and citrinin and screening methods of analysis (OJ L 147, 17.5.2014) 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

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

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

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

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.[65]

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.[66-69.]

A database of additives is available on the European Commission website[70], 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.[71]

Commission Regulation (EU) 2017/324 of 24 February 2017 amended the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 to alter the particle size of specification for basic methacrylate copolymer (E 1205). EFSA advised this is of no safety concern[72].

The 82nd Report of the Joint FAO/WHO Expert Committee on Food Additives, JECFA, WHO Technical Report Series, No. 1000 was published in early 2017.[73] The first part of the report contains a general discussion of the principles governing the toxicological evaluation and assessment of dietary exposure to food additives, including flavouring agents. A summary follows of JECFA's evaluations of technical, toxicological and dietary exposure data for 10 food additives (Allura Red AC; carob bean gum; lutein esters from *Tagetes erecta*; octenyl succinic acid (OSA)-modified gum arabic; pectin; Quinoline Yellow; rosemary extract; steviol glycosides; tartrazine; and xanthan gum) and five groups of flavouring agents (alicyclic, alicyclic-fused and aromatic-fused ring lactones; aliphatic and aromatic amines and amides; aliphatic secondary alcohols, ketones and related esters; cinnamyl alcohol and related substances; and tetrahydrofuran and furanone derivatives). Specifications for the following food additives were revised: aspartame; cassia gum; citric and fatty acid esters of glycerol (CITREM); modified starches; octanoic acid; starch sodium octenyl succinate; and total colouring matters.

Annexed to the report are tables summarizing the Committee's recommendations for dietary exposures to and toxicological evaluations of all of the food additives and flavouring agents considered at this meeting.

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) 2015/2203[74] 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

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65 http://ec.europa.eu/food/food/fAEF/additives/guidance_en.print.htm
66 http://www.legislation.gov.uk/uksi/2013/2210/contents/made
67 http://www.legislation.gov.uk/wsi/2013/2591/contents/made
68 http://www.legislation.gov.uk/ssi/2013/266/contents/made
69 http://www.legislation.gov.uk/nisr/2013/220/contents/made
70 http://ec.europa.eu/food/safety/food_improvement_agents/additives/database_en
71 https://www.food.gov.uk/sites/default/files/multimedia/pdfs/guidance/food-additives-legislation-guidance-to-compliance.pdf
72 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.049.01.0004.01.ENG&toc=OJ:L:2017:049:TOC
73 WHO, World Health Organization http://apps.who.int/bookorders/anglais/detart1.jsp?codlan=1&codcol=10&codcch=1000
74 http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1466676596182&uri=CELEX:32015L2203

4 May 2016.[75] Compositional standards for caseinates are given in the Directive, see section 3.2.1.

2.4.2 Steviol glycosides

Commission Regulation (EU) 2016/441 of 23 March 2016 amended Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council to permit the use of steviol glycosides (E 960) as a sweetener in mustard with a limit of 120 mg kg^{-1} as steviol equivalents.[76] Commission Regulation (EU) 2016/479 of 1 April 2016 amended Annex II to permit the use of steviol glycosides in certain energy-reduced or "with no added sugars" beverages (coffee, tea, cappuccino (maximum 30 mg kg^{-1}) and malt-based and chocolate/cappuccino flavoured (maximum 20 mg kg^{-1}).[77]

Commission Regulation (EU) 2016/1814 of 13 October 2016 amended the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives as regards specifications for steviol glycosides (E 960). The previous specifications stipulated that E 960 contains not less than 95 % of ten named steviol glycosides: stevioside, rebaudiosides A, B, C, D, E and F, steviolbioside, rubusoside and dulcoside, on a dried basis. The specifications further defined the preparations/final product consisting mainly (at least 75 %) of stevioside and/or rebaudioside A. The amendment was on foot of an application to add rebaudioside M, delete the minimum amount of 75 % of stevioside and/or rebaudioside A and expand the lists of chemical names, molecular formulas, molecular weights and CAS numbers to include, in addition to stevioside and rebaudioside A, the other nine steviol glycosides and rebaudioside M. A production process was described that results in a preparation that contains 95 % of steviol glycosides with rebaudioside M representing more than 50 % of the finished product and the remainder comprising the following ten related steviol glycosides in any combination and ratio: stevioside, rebaudiosides A, B, C, D, E, F, dulcoside, steviolbioside and rubusoside. While extracts characterised by a ≥ 95 % content of rebaudioside M contain < 5 % of rebaudiosides D, A and B combined, extracts with a lower rebaudioside M content (approximately 50 %) may comprise close to 40 % rebaudioside D and 7 % rebaudioside A. EFSA concluded that these changes would not be of a safety concern and the specification was changed by the above measure.[78]

Commission Regulation (EU) 2017/335 of 27 February 2017[79] amended Annex II to Regulation (EC) No 1333/2008 to allow the use of steviol glycosides (E 960) as a sweetener in certain energy-reduced confectionery products. Considering that the exposure estimates are below the ADI for all age groups, the proposed uses and use levels were not considered a safety concern, however maximum limits are set out in the regulation

2.4.3 Sucralose

Commission Regulation (EU) 2016/1776 of 6 October 2016 amended Annex II to Regulation (EC) No 1333/2008 to authorise the use of sucralose (E 955) as a flavour enhancer at a maximum level of 1200 mg kg^{-1} in chewing gum with added sugars or polyols (food subcategory 5.3). This use increases the overall intensity of the flavour of the chewing gum and although the additional

[75] 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
[76] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1466595930807&uri=CELEX:32016R0441
[77] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.087.01.0001.01.ENG&toc=OJ:L:2016:087:TOC
[78] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.278.01.0037.01.ENG&toc=OJ:L:2016:278:TOC
[79] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.050.01.0015.01.ENG&toc=OJ:L:2017:050:TOC

use would lead to an increase in its intake this was considered to be minor and therefore not of safety concern.[80]

2.4.4 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 number of foods and beverages. EFSA confirmed that although the toxicological database was limited, the current group ADI of 0.7 mg SO_2 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.[81]

2.4.5 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.[82]

2.4.6 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.[83] The regulation is regularly updated, readers should refer to Eur Lex for the latest version as only major updates are recorded here.

Commission Regulation (EU) 2017/378 of 3 March 2017[84] amended Annex I to Regulation 1334/2008 as regards certain flavouring substances, mainly -dienol and -dienals. EFSA evaluated representative compounds and had concerns on genotoxicity. The parties concerned have carried out further toxicity studies but pending their evaluation Table 1 of Section 2 of Part A of Annex I has been amended to limit the concentrations of the compounds in food, subject to transition periods.

2.5 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. Commission Directive (EU) 2016/1855 of 19 October 2016 amended, following an EFSA assessment, Directive 2009/32/EC to change the maximum residual limit, MRL, for dimethyl ether as an

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[80] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.272.01.0002.01.ENG&toc=OJ:L:2016:272:TOC
[81] http://www.efsa.europa.eu/en/efsajournal/pub/4438
[82] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/576807/Foodfeedlaw_July-Sept_16_Final.pdf
[83] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1445980490072&uri=CELEX:02008R1334-20150729
[84] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.058.01.0014.01.ENG&toc=OJ:L:2017:058:TOC [85] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.284.01.0019.01.ENG&toc=OJ:L:2016:284:TOC

extraction solvent in defatted animal protein products (collagen and collagen derivatives) from 0.009 mg kg^{-1} to 3 mg kg^{-1}, and a new use for dimethyl ether for the extraction of protein products to yield gelatine, with a MRL of 0.009 mg kg^{-1}.[85]

2.6 Food contact materials

Regulation (EC) No 1935/2004[86] 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 (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.[87]

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.[88, 89]

In August 2016 Regulation 10/2009 was extensively amended by Commission Regulation (EU) 2016/1416.[90] Recent EFSA opinions have been incorporated and textual errors corrected, the definition 'hot-fill' has been clarified, and other technical clarifications made.

Commission Regulation 2015/1906[91] 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.

2.6.1 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

[85] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.284.01.0019.01.ENG&toc=OJ:L:2016:284:TOC
[86] See EUR-Lex for up to date versions of legislation: http://eur-lex.europa.eu/homepage.html
[87] 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
[88] http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation/index_en.htm
[89] http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/index_en.htm
[90] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1416
[91] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.278.01.0011.01.ENG

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 2017[92] 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

2.7 Marine biotoxins

The overarching law governing is given in the consultation as Regulation (EC) No 853/2004[93] 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 2006[94] last amended in 2016. In England the Food Safety and Hygiene (England) Regulations 2013 apply[95]. Recognised testing methods for marine biotoxins are described in Annex III of Commission Regulation (EC) No 2074/2005 of 5 December 2005.[96] Further information is available from FSA[97] on shellfish monitoring and fish and shellfish[98] and from Food Standards Scotland[99]. EFSA have published a number of opinions on marine biotoxins and further

[92] 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
[93] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1494593945343&uri=CELEX:02004R0853-20160401
[94] http://www.legislation.gov.uk/ssi/2006/3/regulation/13/made
[95] http://www.legislation.gov.uk/uksi/2013/2996/contents/made
[96] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1494594527755&uri=CELEX:02005R2074-20160603
[97] https://www.food.gov.uk/enforcement/monitoring/shellfish/
[98] https://www.food.gov.uk/business-industry/fish-shellfish
[99] http://www.foodstandards.gov.scot/food-safety-standards/advice-business-and-industry/shellfish

information is also available from the Centre for Environment, Fisheries and Aquaculture Science (Cefas)[100] and the Agri-Food & Biosciences Institute (AFBI)[101].

2.8 Pesticides

Commission Implementing Regulation 2015/595[102] sets out a coordinated multiannual control programme of the EU for 2016, 2017 and 2018 to ensure compliance with maximum residue levels (MRLs) of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

Regulation (EC) No 396/2005 governs 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.[103, 104]

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.[105] Regulation 1107/2009 is implemented by Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011[106] which is frequently updated.

2.8.1 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.[107]

2.9 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.

2.10 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.

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[100] https://www.cefas.co.uk/
[101] https://www.afbini.gov.uk/articles/marine-biotoxins-shellfish
[102] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.099.01.0007.01.ENG
[103] http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN
[104] http://ec.europa.eu/food/plant/pesticides/max_residue_levels/index_en.htm
[105] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474202948544&uri=CELEX:02009R1107-20140630 (but see EUR-Lex for latest version)
[106] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474199567547&uri=CELEX:32011R0540 (but see EUR-Lex fro latest version)
[107] https://echa.europa.eu/regulations/biocidal-products-regulation

Council Regulation (Euratom) 2016/52[108] 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 Welsh private water supply regulations covering monitoring of radioactivity in water (see section 2.15).

2.11 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 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.[109]

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.[110]

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.[111]

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.[112]

2.12 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

[108] 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
[109] http://ec.europa.eu/food/safety/biosafety/food_borne_diseases/tse_bse/index_en.htm
[110] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1396
[111] 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
[112] 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

chain. An editorial published in the EFSA Journal in January 2017 describes how to use the database.[113]

2.13 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 2015[114] and, in Northern Ireland, by the Animal and Animal Products (Examination for Residues and Maximum Residue Limits) (Northern Ireland) 2016 (SR 54).[115]

Regulation (EU) No 37/2010 is regularly amended as regards MRLs. Further information is available from the European Medicines Agency (EMA)[116] and on the European Commission website.[117] 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 Food and Agriculture Organization of the United Nations, FAO, and the World Health Organization, WHO.[118]

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.[119]

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).[120]

2.14 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)

[113] http://www.efsa.europa.eu/en/press/news/170118-0
[114] http://www.legislation.gov.uk/uksi/2015/787/pdfs/uksi_20150787_en.pdf
[115] http://www.legislation.gov.uk/nisr/2016/54/pdfs/nisr_20160054_en.pdf
[116] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000165.jsp
[117] http://ec.europa.eu/health/documents/community-register/index_en.htm
[118] http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/
[119] 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
[120] 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

thorough cooking and (d) immediate chilling after cooking. These are summarised as 'cook, chill, clean, separate'.[121] HACCP (Hazard Analysis and Critical Control Point) is a key system that helps food business operators address food hygiene.[122] Food Hygiene is controlled legislatively by Food Safety and Hygiene Regulations, currently the Food Safety and Hygiene (England) Regulations 2013[123] with equivalents in Wales,[124] Scotland[125] and Northern Ireland.[126] 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.[127] Guidance on microbiological criteria is available from Public Health England[128] and from IFST on aspects such as Shigatoxin-producing *E. coli*, fresh produce safety, foodborne viral infections, campylobacter, cyclospora, and cryptosporidium.[129]

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.[130-133]

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.[134] The incident attracted considerable publicity.

2.14.1 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.[135]

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 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)[136] which came into force on 28 November 2016 and The Food Hygiene Rating Act (Northern Ireland) 2016.[137] 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. The Food Hygiene Rating Regulations (Northern

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[121] https://www.food.gov.uk/business-industry/food-hygiene
[122] https://www.food.gov.uk/business-industry/food-hygiene/haccp
[123] http://www.legislation.gov.uk/uksi/2013/2996/note/made
[124] Food Hygiene (Wales) Regulations 2006 with many subsequent amendments
[125] Food Hygiene (Scotland) Regulations 2006 with many subsequent amendments
[126] The Food Hygiene Regulations (Northern Ireland) 2006 with many subsequent amendments
[127] https://www.food.gov.uk/business-industry/guidancenotes/hygguid/microbiolreg
[128] PHE, 2009, Ready-to-eat foods: microbiological safety assessment guidelines https://www.gov.uk/government/publications/ready-to-eat-foods-microbiological-safety-assessment-guidelines
[129] http://www.ifst.org/knowledge-centre/information-statements
[130] The Food Safety and Hygiene (England) (Amendment) Regulations 2016 http://legislation.data.gov.uk/uksi/2016/868/made/data.pdf
[131] The Food Hygiene (Wales) (Amendment) Regulations 2016, http://www.legislation.gov.uk/cy/wsi/2016/845/made
[132] The Food Hygiene (Scotland) Amendment Regulations 2016 http://www.legislation.gov.uk/ssi/2016/260/pdfs/ssi_20160260_en.pdf
[133] http://www.legislation.gov.uk/nisr/2016/345/contents/made
[134] http://www.hps.scot.nhs.uk/pubs/detail.aspx?id=3200
[135] https://www.food.gov.uk/business-industry/hygieneratings
[136] http://www.legislation.gov.uk/wsi/2016/429/pdfs/wsi_20160429_mi.pdf
[137] Food Hygiene Rating Act (Northern Ireland) 2016, Ch 3 http://origin-www.legislation.gov.uk/nia/2016/3/enacted

Ireland) 2016 no. 313[138] and the Food Hygiene Rating (Transitional Provisions) Order (Northern Ireland) 2016 no. 314[139] 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.[140] 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 made[141] 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).

2.15 Water for human consumption

Legislation on water for human consumption is noted here, whether or not regarded as "food".

The primary EU law on supplied water is Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, alongside Directive 2009/54/EC on the exploitation and marketing of natural mineral waters[142] (recast)[143] 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.[144]

Domestic implementation of the latter two is by:

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

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015[145,146] 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

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[138] http://www.legislation.gov.uk/nisr/2016/313/made
[139] http://www.legislation.gov.uk/nisr/2016/314/made
[140] http://www.legislation.gov.uk/nisr/2016/328/made/data.pdf
[141] http://www.legislation.gov.uk/nisr/2016/425/pdfs/nisr_20160425_en.pdf
[142] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1453734625466&uri=CELEX:32009L0054
[143] Which repeals and replaces Directive 80/777/EEC.
[144] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1453734764128&uri=CELEX:32003L0040
[145] http://www.legislation.gov.uk/ssi/2015/363/pdfs/ssi_20150363_en.pdf
[146] http://www.legislation.gov.uk/ssi/2015/363/pdfs/ssics_20150363_en.pdf correction slip

requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (OJ L 296, 7.11.13, p.12). Regulation 3 makes consequential amendments to the interpretation provisions in regulation 2 of the 2007 Regulations. Regulation 4 amends regulation 16 of the 2007 Regulations to specify the monitoring and sampling requirements required by Food Authorities. Similar legislation has been enacted in Wales by the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015[147] (SI 1867, W274) and in Northern Ireland with the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2015[148] (SR 365).

Commission Directive 2015/1787[149] 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)[150] 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 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,[151] 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

147 http://www.legislation.gov.uk/wsi/2015/1867/pdfs/wsi_20151867_mi.pdf
148 http://www.legislation.gov.uk/nisr/2015/365/pdfs/nisr_20150365_en.pdf
149 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.260.01.0006.01.ENG
150 http://www.assembly.wales/laid%20documents/sub-ld10651/sub-ld10651-e.pdf
151 http://www.legislation.gov.uk/uksi/2016/614/pdfs/uksi_20160614_en.pdf

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, coming into force 27 June 2016.[152] They revoke and replace the Private Water Supplies Regulations 2009 (SI 2009/3101).

2.16 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.[153]
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[154] as well as Home Office guidance for local authorities on taking action against "head shops" selling psychoactive substances,[155] and Home Office guidance for retailers.[156] 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

[152] http://www.legislation.gov.uk/uksi/2016/618/contents/made
[153] http://www.legislation.gov.uk/ukpga/2016/2/contents/enacted
[154] https://www.gov.uk/government/collections/psychoactive-substances-bill-2015
[155] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/410961/Guidance_for_local_authorities_on_taking_action_against_10.03_15.pdf
[156] https://www.gov.uk/government/publications/psychoactive-substances-act-guidance-for-retailers/psychoactive-substances-act-2016-guidance-for-retailers

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 Strategy[157] 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,[158] the Psychoactive Substances Act 2016 (Commencement) Regulations 2016[159] and the Magistrates' Courts (Psychoactive Substances Act 2016) (Transfer of Proceedings) Rules 2016.[160]

The Psychoactive Substances Act 2016 (correction slip) noted Schedule 5, paragraph 8(2): "1A" should read "1ZA".[161]

Regulation (EU) No 1307/2013 of the European Parliament and of the Council (Article 32(6)) provides that in order to prevent support 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 %. Following a further year of testing of the hemp variety 'Finola', which was initially prohibited in the UK, the THC limit was not exceeded and the prohibition was lifted by Commission Implementing Decision (EU) 2016/1925 of 31 October 2016 repealing Implementing Decision (EU) 2016/17 authorising the United Kingdom to prohibit on its territory the marketing of a variety of hemp listed in the Common Catalogue of varieties of agricultural plant species, pursuant to Council Directive 2002/53/EC.[162]

Commission Recommendation (EU) 2016/2115[163] 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. The method of analysis is preferably chromatographic separation coupled with mass spectrometry (LC-MS or GC-MS) following an appropriate clean-up step (liquid-liquid or solid phase extraction, SPE). Preference should be given to chromatographic techniques that allow the determination of Δ^9-THC separately, its precursors and other cannabinoids in hemp-containing food products. The data are to be provided to EFSA pursuant to its opinion on the risks for human health related to the presence of THC in milk and other food of animal origin.[164]

Council Implementing Decision (EU) 2017/369[165] of 27 February 2017 signals control measures in some member state's national law for the 'illegal high' methyl 2-[[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA) as soon as possible but no later than 4 March 2018. The UK is not bound by the overarching legislation, Decision 2005/387/JHA, and is not adopting the Decision. The risk-assessment report on the new psychoactive MDMB-CHMICA was drawn up in accordance with Decision 2005/387/JHA by the European Monitoring Centre for Drugs and Drug Addiction, and was subsequently submitted to the Commission and to the Council on 28 July 2016. MDMB-CHMICA is a synthetic cannabinoid receptor agonist available on the drug market in the EU since at least August 2014 and has been

[157] https://www.gov.uk/government/publications/circular-0042016-psychoactive-substances-act-2016
[158] http://www.legislation.gov.uk/uksi/2016/554/regulation/2/made
[159] http://www.legislation.gov.uk/uksi/2016/553/contents/made
[160] http://www.legislation.gov.uk/uksi/2016/546/made
[161] http://www.legislation.gov.uk/ukpga/2016/2/pdfs/ukpgacs_20160002_en.pdf
[162] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.293.01.0002.01.ENG&toc=OJ:L:2016:293:TOC
[163] 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
[164] https://www.efsa.europa.eu/en/efsajournal/pub/4141
[165] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.056.01.0210.01.ENG&toc=OJ:L:2017:056:TOC

detected in 23 Member States. The high potency of MDMB-CHMICA and the highly variable amounts, and 'hot spots' of the compound in 'legal high' products constitute a high risk of acute toxicity. Multiple reports have indicated a possibility for violence and aggression as a consequence of its use. In addition, the detection of MDMB-CHMICA in cases of suspected driving under influence indicates a potential for wider risk to public safety. Eight Member States have reported a total of 28 deaths and 25 acute intoxications where MDMB-CHMICA was detected. It is typically administered by smoking a herbal mixture. MDMB-CHMICA is not listed for control under the 1961 United Nations Single Convention on Narcotic Drugs or under the 1971 United Nations Convention on Psychotropic Substances. However, it is listed among the substances considered for review at the 38th WHO Expert Committee on Drug Dependence which makes recommendations to the United Nations Commission on Narcotic Drugs on the control measures that it considers appropriate.

Council Decision (EU) 2017/449 of 7 March 2017[166] set out the position to be adopted, on behalf of the European Union, in the 60th session (March 2017) of the Commission on Narcotic Drugs on the scheduling of substances under the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971. The substances U-47700 (3,4-dichloro-N-(2-dimethylamino-cyclohexyl)-N-methyl-benzamide), a compound liable to similar abuse as and with similar ill-effects to those of controlled opioids, and butyrfentanyl are to be included in Schedule I of the 1961 Convention. Schedule II of the 1971 Convention on Psychotropic Substances is to have added: 4-MEC (4-methylethcathinone), ethylone, pentedrone (α-methylaminovalerophenone), ethylphenidate (EPH), methiopropamine (MPA), MDMB-CHMICA, (methyl N-{[1-(cyclohexylmethyl)-1H-indol-3-yl]carbonyl}-3-methyl-L-valinate) for which fatalities have been reported, 5F-APINACA (5F-AKB48) (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide) and XLR-11 (1-(5-fluoropentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone) for which adverse events including one death have been recorded.

For further details on previous international developments see section 2.14 in a previous edition of this report.[167]

2.17 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.[168] 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.[169] 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.[170] 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

[166] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.069.01.0025.01.ENG&toc=OJ:L:2017:069:TOC
[167] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/576807/Foodfeedlaw_July-Sept_16_Final.pdf
[168] Walker, D. R. (2015), Report on the Regulation of Herbal Medicines and Practitioners, 26 March 2015, http://www.dcscience.net/Report_on_Regulation_of_Herbal_Medicines_and_Practitioners.pdf (Accessed 17.09.2016)
[169] Directive 2001/83/EC http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474128484290&uri=CELEX:02001L0083-20121116
[170] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474128379997&uri=CELEX:32004L0024

21 November 2008.[171] This list is periodically updated; see for example (non-exhaustively) Commission Implementing Decision (EU) 2016/1659 of 13 September 2016[172] 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 traditional herbal medicines is updated regularly.[173] A list of banned or restricted herbal products, including for example aconite, belladonna, kava-kava and ragwort, is available.[174]

Periodic assessment of herbal products takes place, for example recently the International Agency for Research on Cancer, IARC, of the World Health Organization 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).[175, 176]

3 Consumer choice

This section covers (3.1) labelling (3.2) composition (3.3) food fraud/food crime, (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 1169/2011[177] 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.[178] Domestic implementation is effected in England by the Food Information Regulations (SI 2014 No 1855),[179] in Northern Ireland by the Food Information Regulations (Northern Ireland) 2014 (SR 2014 No 223)[180] and, in Wales the Food Information Regulations (Wales) 2014 (SI 2014 No 2303, W227).[181] In Scotland implementation is by the Food Information Regulations (Scotland) 2014 (SSI 312)[182] which were amended in December 2015 by the Food Information (Miscellaneous Amendments) (Scotland) Regulations 2015 (SSI 410).[183] 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.[184] Guidance on nutrition labelling is also available on the Commission website.[185]

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[171] http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm
[172] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1659
[173] https://www.gov.uk/government/publications/herbal-medicines-granted-a-traditional-herbal-registration-thr
[174] https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients
[175] http://monographs.iarc.fr/ENG/Monographs/vol108/mono108.pdf
[176] Grosse *et al*., *The Lancet Oncology*, 14, 807 – 808, http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045%2813%2970329-2/fulltext
[177] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF
[178] http://www.reading.ac.uk/foodlaw/label/links.htm
[179] http://www.legislation.gov.uk/uksi/2014/1855/pdfs/uksi_20141855_en.pdf
[180] http://www.legislation.gov.uk/nisr/2014/223/pdfs/nisr_20140223_en.pdf
[181] http://www.legislation.gov.uk/wsi/2014/2303/pdfs/wsi_20142303_mi.pdf
[182] http://www.legislation.gov.uk/ssi/2014/312/pdfs/ssi_20140312_en.pdf
[183] http://www.legislation.gov.uk/ssi/2015/410/pdfs/ssi_20150410_en.pdf
[184] http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/proposed_legislation_en.htm
[185] http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm

3.1.1 Country of origin labelling

The Country of Origin of Certain Meats (England) Regulations 2015 (SI 518)[186] modified certain provisions of the Food Safety Act 1990, and implemented Articles 3 to 6 and 8 of Commission Implementing Regulation (EU) No 1337/2013 regarding the provenance or country of origin of certain types of meats (fresh, chilled and frozen meat of swine, sheep, goats and poultry). Please see our July – September 2015 report for further detail.[187]

Similar legislation has been enacted in Northern Ireland through The Country of Origin of Certain Meats Regulations (Northern Ireland) 2015[188] (SR 321) and in Wales by the Country of Origin of Certain Meats (Wales) Regulations 2015[189] (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.[190]

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).[191]

3.1.3 Defra food labelling guidance

Defra have published guidance on the information that must be provided with food products to comply with the European Food Information to Consumers Regulation No 1169/2011 (FIC) and the Food Information Regulations 2014 (FIR).[192]

3.1.4 Organic food

The principal measure is Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products.

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

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[186] http://www.legislation.gov.uk/uksi/2015/518/pdfs/uksi_20150518_en.pdf
[187] https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2015
[188] http://www.legislation.gov.uk/nisr/2015/321/pdfs/nisr_20150321_en.pdf
[189] http://www.legislation.gov.uk/wsi/2015/1519/pdfs/wsi_20151519_mi.pdf
[190] https://www.food.gov.uk/northern-ireland/news-updates/news/2016/15025/voluntary-labelling-of-country-of-origin
[191] http://ec.europa.eu/fisheries/documentation/publications/eu-new-fish-and-aquaculture-consumer-labels-pocket-guide_en.pdf
[192] https://www.gov.uk/guidance/food-labelling-giving-food-information-to-consumers

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.[193]

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.[194]

3.1.5 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.[195]

3.1.6 Protected names and quality schemes

There are three protection marks in the EU:[196]

- 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.[197]

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[198].

3.2 Composition

3.2.1 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.[199] 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

[193] https://www.gov.uk/government/publications/organic-certification-list-of-uk-approved-organic-control-bodies
[194] 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
[195] 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
[196] http://ec.europa.eu/agriculture/quality/schemes/index_en.htm
[197] https://www.gov.uk/guidance/eu-protected-food-names-how-to-register-food-or-drink-products
[198] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1488746464115&uri=CELEX:02012R1151-20130103
[199] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1481228098768&uri=CELEX:32015L2203

('Codex standard for edible casein products').[200] Domestic implementation was formalised in late 2016 by the Caseins and Caseinates (Wales) Regulations 2016 No.1130 (W.270)[201] and the Caseins and Caseinates Regulations (Northern Ireland) 2016 No.415.[202] The Caseins and Caseinates (Scotland) Regulations 2016 No.383[203] were made but were replaced on 15 December 2016 by the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016[204] owing to defects in S.S.I. 2016/383. 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.

3.2.2 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.[205]

3.2.3 Honey

The making and coming into force of the Honey (Wales) Regulations 2015[206] (SI 1507, W174) completed the updating of domestic implementation of Council Directive 2001/110/EC relating to honey.[207] These regulations sit alongside the Honey (Scotland) Regulations 2015 (SSI 208),[208] the Honey Regulations (Northern Ireland) 2015 (SR 261),[209] and the Honey Regulations (England) 2015[210] (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.

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[200] 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

[201] http://legislation.data.gov.uk/wsi/2016/1130/contents/made/data.htm?wrap=true

[202] http://www.legislation.gov.uk/nisr/2016/415/contents/made

[203] http://www.legislation.gov.uk/ssi/2016/383/pdfs/ssi_20160383_en.pdf

[204] http://www.legislation.gov.uk/ssi/2016/422/pdfs/ssi_20160422_en.pdf

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

[206] http://www.legislation.gov.uk/wsi/2015/1507/pdfs/wsi_20151507_mi.pdf

[207] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1445979649018&uri=CELEX:02001L0110-20140623

[208] http://www.legislation.gov.uk/ssi/2015/208/contents/made

[209] http://www.legislation.gov.uk/nisr/2015/261/contents/made

[210] http://www.legislation.gov.uk/uksi/2015/1348/pdfs/uksi_20151348_en.pdf

3.2.4 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.[211] 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 products, silkworms, and other products. The Single Common Market Organisation (Consequential Amendments) Regulations 2013[212] 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 2016[213] amending minor drafting errors in the 2013 regulations.

3.2.5 Meat products

The Products Containing Meat etc. Regulations 2014 enacted in England (e.g. SI 3001/2014[214]), 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).[215]

Similar Regulations have been enacted in Scotland with the Products Containing Meat etc. Regulations (Scotland) Regulations 2014 (SSI 289/2014)[216] which revokes the Meat Products (Scotland) Regulations 2004 (SSI 6/2004), the Meat Products (Scotland) Amendment Regulations 2008(SSI 97/2008) and regulation 18(4) of the Food Additives (Scotland) Regulations 2009(SSI 436/2009), and in Northern Ireland with the Products Containing Meat etc. Regulations (Northern Ireland) 2014[217] (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).[218]

3.2.6 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. In July 2016 Commission Implementing Regulation (EU) 2016/1227 amended methods for the determination of free acidity and the organoleptic assessment of virgin olive oils.[219] Commission Implementing Regulation (EU) 2016/1784 of 30 September 2016 replaced the text of the method for the determination of

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[211] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32013R1308
[212] http://www.legislation.gov.uk/uksi/2013/3235/pdfs/uksi_20133235_en.pdf
[213] http://www.legislation.gov.uk/uksi/2013/3235/made
[214] http://www.legislation.gov.uk/uksi/2014/3001/pdfs/uksi_20143001_en.pdf
[215] https://www.gov.uk/government/publications/food-and-feed-law-legislation-review
[216] http://www.legislation.gov.uk/ssi/2014/289/pdfs/ssi_20140289_en.pdf
[217] http://www.legislation.gov.uk/nisr/2014/285/pdfs/nisr_20140285_en.pdf
[218] http://www.legislation.gov.uk/ssi/2016/24/pdfs/ssi_20160024_en.pdf
[219] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1227

peroxide value.[220] Commission Delegated Regulation (EU) 2016/2095 of 26 September 2016 amended the limit values for fatty acid ethyl ester, heptadecanoic, heptadecenoic, eicosenoic acids and the specific extinction coefficient at wavelength 270 nm.[221]

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.[222]

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.[223]

Guidance on olive oil composition, characteristics and labelling is available from Defra.[224]

Council Decision (EU) 2016/1892 of 10 October 2016 noted the signing on behalf of the European Union and provisional application of the International Agreement on Olive Oil and Table Olives, 2015.[225, 226]

3.2.7 Spices

The 3rd Session of the Codex Committee on Spices and Culinary Herbs was held from 6–10 February 2017 in Chennai, India. Documents and draft standards for various spices are available.[227]

3.2.8 Spirit drinks etc.

Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 controls the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks.[228]

On 1 July 2016 Commission Regulation (EU) 2016/1067 amended Annex III to Regulation (EC) No 110/2008 on geographical indications (such as *Scotch Whisky*). Pursuant to Article 20(1) of Regulation 110/2008, Member States were to submit to the Commission a technical file for each established geographical indication however 87 geographical indication files were not submitted by the deadline and have been removed from Annex III. The remaining geographical indications will be assessed but in the meantime are listed in Regulation 2016/1067.[229]

Commission Regulation (EC) No 2870/2000 lists and describes the reference methods for the analysis of spirit drinks.

[220] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1478632817122&uri=CELEX:32016R1784
[221] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.326.01.0001.01.ENG&toc=OJ:L:2016:326:TOC
[222] http://origin-www.legislation.gov.uk/uksi/2014/195/contents/made
[223] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1080
[224] https://www.gov.uk/guidance/olive-oil-regulations-and-inspections
[225] http://unctad.org/en/PublicationsLibrary/suc2015d5_en.pdf
[226] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.293.01.0002.01.ENG&toc=OJ:L:2016:293:TOC
[227] http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCSCH&session=3
[228] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474277348569&uri=CELEX:02008R0110-20160705
[229] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1067

3.2.9 Wine

Wine law is complex and extensive; a readable guide is on the FSA website with links to European legislation.[230] Regulation 1308/2013 on the common organisation of the markets in agricultural products also applies, (see section 3.2.4).

Commission Implementing Regulation (EU) 2016/2147[231] of 7 December 2016 authorised an increase of the limits for the enrichment of wine produced using the grapes harvested in 2016 in certain wine-growing regions of Germany and in all wine-growing regions of Hungary. Enrichment is usually by adding sucrose, concentrated grape must or rectified concentrated grape must, or by partial concentration, including reverse osmosis or through cooling (Art. 80 and Annex VIII Regulation 1308/2013.)

3.3 Food fraud/food crime

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 Commission[232] 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 and the Commission in cases of suspected food fraud.[233] 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.[234]

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.[235]

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.[236]

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[230] https://www.food.gov.uk/business-industry/winestandards/lawguide
[231] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.333.01.0030.01.ENG&toc=OJ:L:2016:333:TOC
[232] http://ec.europa.eu/food/safety/official_controls/food_fraud/horse_meat/index_en.htm
[233] http://ec.europa.eu/food/safety/official_controls/food_fraud/index_en.htm
[234] http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm
[235] 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
[236] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1436450297142&uri=CELEX:02003R1829-20080410

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[237]. Labelling, environmental and post-market monitoring, a detection method and reference material are normally detailed in the Decisions.

Previous Commission Decisions regulated the withdrawal from the market of certain genetically modified hybrid oilseed rape, hybrid oilseed rape and Topas and oilseed rape as well as their derived products after the authorisation holder, Bayer CropScience AG, indicated that it had no intention of submitting an application for the renewal of the authorisation. A transitional period of five years was allowed during which food and feed containing, consisting of or produced from this GM material were allowed to be placed on the market in a proportion no higher than 0.9 % provided that that presence was adventitious or technically unavoidable. The purpose of that transitional period was to take into account the fact that traces of that GM material could sometimes be present, even after Bayer CropScience AG had stopped selling seeds. In view of continuing traces found possibly as a result of dormancy in the soil and spillages during previous harvests the transition period has been extended to 31 December 2019, provided that the GM material is present adventitiously or is technically unavoidable and is in a proportion no higher than 0.1 % mass fraction. In addition Bayer CropScience AG shall ensure the availability of certified reference material for ACS-BNØØ4-7×ACS-BNØØ1-4 oilseed rape via the American Oil Chemists Society at https://www.aocs.org/attain-lab-services/certified-reference-materials-(crms)[238]

In an interesting Judgment of the General Court of 15 December 2016, TestBioTech and Others* v Commission, (Case T-177/13)[239] the applicants sought an internal review of the decision on marketing authorisation of genetically modified soybean MON 87701 x MON 89788 however the court dismissed the action.
*European Network of Scientists for Social and Environmental Responsibility and Sambucus.

3.4.1 Cultivation of GMOs

Commission Directive 2015/412[240] amends Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. This devolves responsibility in this matter to Member States. See our previous quarterly report[241] 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

[237] http://ec.europa.eu/food/plant/gmo_en
[238] Commission Implementing Decision (EU) 2016/2268 of 14 December 2016 amending Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC as regards the tolerance period for traces of Ms1×Rf1 (ACS-BNØØ4-7×ACS-BNØØ1-4) hybrid oilseed rape, Ms1×Rf2 (ACS-BNØØ4-7×ACS-BNØØ2-5) hybrid oilseed rape and Topas 19/2 (ACS-BNØØ7-1) oilseed rape, as well as their derived products *(notified under document C(2016) 8390)*
[239] http://www.bailii.org/eu/cases/EUECJ/2016/T17713.html
[240] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.068.01.0001.01.ENG
[241] https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2015

from clones as novel foods. However, the European Commission and both the European Food Safety Authority and the UK Food Standards Agency 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 Committee believes that both UK and EU policy should be based on evidence, and as such does 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 notes that, in past trials, some cloned progeny have not developed normally, leading to significant welfare problems and premature death.[242]

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.[243] 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 due to be 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.[244] A Commission Q&A is available[245] and a list of authorisations.[246] 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.[247]

3.6.1 Fermented soybean extract

Commission Implementing Decision (EU) 2017/115 of 20 January 2017[248] authorised the placing on the market of fermented soybean extract as a novel food ingredient under Regulation (EC) No 258/97. EFSA has advised that fermented soybean extract used in food supplements intended for adults is safe under the conditions of use proposed by the applicant limiting consumption per day to a maximum dose of 100 mg. EFSA further advised that fermented soybean extract contains nattokinase which exhibits *in vitro* fibrinolytic activity and *in vivo* thrombolytic activity in animals when administered parenterally. It is therefore necessary to inform consumers about the need of medical supervision in cases when fermented soybean extract is consumed in combination with medication. These conditions are enforced by the regulation.

3.6.2 Lactitol

In 2015 DuPont Nutrition Biosciences ApS made a request to the competent authorities of Denmark to place lactitol on the EU market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97, [foods and food ingredients with a new or intentionally modified primary molecular structure]. The company proposed lactitol to be used in the same food categories and levels currently permitted when lactitol is used as a food additive. The competent food assessment body of Denmark came to the conclusion that lactitol meets the

[242] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/524769/fangr-cloning-farm-animals-statement.pdf
[243] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/332618/Cloned_animal_report.pdf
[244] 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
[245] http://europa.eu/rapid/press-release_MEMO-15-5875_en.htm
[246] http://ec.europa.eu/food/safety/novel_food/authorisations/list_authorisations/index_en.htm
[247] https://www.efsa.europa.eu/en/press/news/161110
[248] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.018.01.0050.01.ENG&toc=OJ:L:2017:018:TOC

criteria for novel food ingredients set out in Article 3(1) of Regulation (EC) No 258/97. However some Member States raised concerns regarding excess of lactitol intake, as it is a laxative. Therefore it was decided to restrict the use of lactitol to food supplements. Hence Commission Implementing Decision (EU) 2017/450 of 13 March 2017[249] permits lactitol to be placed on the market as a novel food ingredient to be used in food supplements in capsule or tablet form intended for the adult population with a maximum dose of 20 g lactitol per day as recommended by the manufacturer.

3.7 Consumer attitudes

The Food Standards Agency 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,[250] 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%).

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 Food Standards Agency'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%).

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.[251, 252]

[249] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.069.01.0031.01.ENG&toc=OJ:L:2017:069:TOC
[250] https://www.food.gov.uk/news-updates/news/2017/16111/latest-food-and-you-survey-report-published
[251] https://www.gov.uk/government/publications/consumer-rights-act-2015/consumer-rights-act-2015
[252] http://www.which.co.uk/consumer-rights/regulation/consumer-rights-act

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.[253]

Guidance on nutrition labelling is available on the Commission website.[254] Commission Regulation (EU) No 432/2012 established the list of permitted health claims and started to apply from 14 December 2012.[255] The EU Register of nutrition and health claims is also available[256] hence successive amendments to Regulation 432/2012 are not usually recorded here unless a change is made that requires further explanation.

An example of the complexities of nutrition claims regulation is a case that occurred in August 2016 when Commission Regulation (EU) 2016/1413[257] 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

[253] http://ec.europa.eu/food/safety/labelling_nutrition/claims/refit/index_en.htm
[254] http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm
[255] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012R0432
[256] http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/index_en.htm
[257] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1413

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.[258]

The assessment of some botanical claims is 'on hold'[259] 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).[260, 261, 262]

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 conform with the provisions of the former decree, can still be placed on the market until 20 February 2019.[263]

4.1.1 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.[264]

4.2 Food for infants & 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

[258] https://www.gov.uk/government/publications/nutritional-and-health-claims-legislation-bulletins-2015
[259] For further information see Walker, M. J. (2017), Health and nutrition claims – guidance, regulation and self-regulation. *Nutrition Bulletin*, 42, 69–79
[260] 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
[261] http://curia.europa.eu/juris/document/document.jsf?docid=174170&doclang=en
[262] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62015CO0637
[263] http://www.foodcomplianceinternational.com/blog/2017/2/15/new-belgian-belfrit-decree-on-botanicals-applicable
[264] 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

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 infant and follow-on formulae. Commission Delegated Regulation 2016/127[265] 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 2016/128[266] 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.[267] 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 English[268] and Welsh[269] 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 Ireland[270] 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.[271]

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[265] 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
[266] 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
[267] http://www.legislation.gov.uk/ssi/2016/190/contents/made
[268] The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 http://www.legislation.gov.uk/uksi/2016/688/pdfs/uksi_20160688_en.pdf
[269] The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 http://www.assembly.wales/laid%20documents/sub-ld10709/sub-ld10709-e.pdf
[270] The Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016http://www.legislation.gov.uk/nisr/2016/251/made
[271] http://www.legislation.gov.uk/uksi/2017/62/contents/made

4.3 Sugar

Sugar continues to be a topic of keen current interest. In October 2015 Public Health England, PHE, published[272] 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,[273] 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.[274]

4.4 Food supplements

A useful summary by the Department of Health on legislation relating to the sale of food supplements is available.[275]

4.5 Drug and alcohol addiction, and obesity: effects on employment

In December 2016 an independent review by Dame Carol Black explored the challenges faced by individuals who are addicted to alcohol or drugs, or are obese, when they seek to enter, return to and/or remain in work. These three health conditions impose great costs, on individuals and on society, and they bring with them significant labour market disadvantages for those affected. The problems of drug and alcohol dependence have some common features. Obesity is different and far more common; the labour market consequences are more indirect.[276]

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[277], the Food Standards Act

[272] https://www.gov.uk/government/news/new-evidence-review-of-measures-to-reduce-sugar-consumption
[273] http://www.legislation.gov.uk/nia/2016/26/pdfs/nia_20160026_en.pdf
[274] https://publichealthmatters.blog.gov.uk/2017/03/30/expert-interview-new-guidelines-for-industry-on-the-sugar-reduction-programme/
[275] https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs .
[276] https://www.gov.uk/government/publications/drug-and-alcohol-addiction-and-obesity-effects-on-employment-outcomes
[277] http://www.legislation.gov.uk/ukpga/1990/16/contents and see also The Food Safety Act 1990 (Consequential Modifications) (Scotland) Order 1990

1999[278] 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 section 6.1. See also section 5.4 below. 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*)[279], and Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls …(*etc*)[280].

Modernisation of European food and feed law took a significant step forward in February 2017 with two documents:

- Position (EU) No 1/2017 of the Council at First Reading[281] … and
- Statement of the Council's reasons[282] …:

  with a view to the adoption of a Regulation of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products …,

The second document is relatively short, explains some of the recent history of the process and suggests that the European Commission, Parliament and Council of Ministers have reached political agreement on a compromise text for a new all-encompassing Regulation on food controls.

The general objective of the proposed Regulation is to simplify and streamline the existing legal framework of Regulation (EC) No 882/2004, encompassing almost all sectors of the agri-food chain in a unique set of rules applicable to official controls. Some sectors, for example plant health, plant reproductive material, animal by-products or organic production, currently have separate rules on controls. Therefore the Commission proposed to enlarge the scope of the existing legal framework to incorporate those sectors as well as to make clear that organic production, protected designations of origin, protected geographical indications and traditional specialities guaranteed, and genetically modified organisms (GMOs) were covered. The Council considered it was too early to include plant reproductive material[283] pending a new Commission proposal in this area, agreed to limit GMO controls to feed and food production and clarified that Regulation (EU) No 1308/2013 (Common organisation of the market in agricultural products, see section 3.2.4), should only be included when fraudulent or deceptive practices regarding marketing standards are identified during checks pursuant to Article 89 of that Regulation.

The Regulation also aims to improve the efficiency of official controls performed by the Member States along the agri-food chain so as to allow for quick responses in crisis situations, while minimising the burden for operators; to that end, it requests that such controls be performed on all operators, on a risk basis and with appropriate frequency.

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

278 http://www.legislation.gov.uk/ukpga/1999/28/contents
279 http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1488723013503&uri=CELEX:02002R0178-20140630
280 http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1488722763430&uri=CELEX:02004R0882-20170216
281 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.055.01.0001.01.ENG&toc=OJ:C:2017:055:TOC
282 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.055.01.0143.01.ENG&toc=OJ:C:2017:055:TOC
283 The EU regulates the marketing of plant reproductive material of agricultural, vegetable, forest, fruit and ornamental species and vines, with criteria for health and quality; legislation applies to genera and species important for the internal market and is based on registration and certification of seeds etc, see http://ec.europa.eu/food/plant/plant_propagation_material_en

Although much of the proposed Regulation will be familiar to those conversant with Regulation 882/2004 it is difficult to do full justice to the Position statement, which runs to 99 recitals and 167 Articles. However, relatively briefly, it lists the wide range of measures within the EU on official controls and explains that, pursuing rationalisation, simplification and better regulation, official controls should be integrated into a single legislative framework. For that purpose, Regulation (EC) No 882/2004 and other Union acts currently governing official controls in specific areas should be repealed and replaced. The recitals draw attention to the attributes expected of national competent authorities such as acting in the public interest, appropriately resourced and equipped, impartiality and professionalism, and training demonstrating the quality, consistency and effectiveness of official controls. Competent authorities should carry out independently scrutinised transparent audits to ascertain compliance. Food businesses should have, and be made aware of, the right, subject to national law, to appeal against the decisions taken by the competent authorities. The frequency of official controls, which should be mainly un-announced, and the scientific standards for sampling and testing and delegation of controls are covered.

The proposed Regulation envisages recovery of costs for official controls from businesses with non-compliant businesses paying more than compliant ones and a series of administrative rules are elaborated in the draft. There was some disagreement between the Commission and the Council on the current fixed mandatory fee system in some sectors (e.g. meat) however the Council considered no change in the fee system was necessary but agreed that Member States willing to charge fees at the level of the costs incurred and not at a fixed level would have to follow harmonised rules on cost coverage and calculation methods, with enhanced transparency and consultation with relevant stakeholders

Following a strong request from the European Parliament, the Council agreed to include in the Regulation provisions obliging Member States to have in place mechanisms to enable the reporting of actual or potential infringements of the Regulation, the follow-up of such reporting and the protection of the persons reporting against retaliation, discrimination or unfair treatment (Article 140).

The draft Regulation includes in its Article 35 text that rehearses and extends the familiar provision of Article 11(5) of Regulation 882/2004 on supplementary expert opinion, now referred to as ‘second expert opinion’. As the UK has long had in place the Government Chemist providing a referee analyst function it is worth reproducing the new proposed text in full since it envisages elements not explicitly included in the extant Article 11(5) (such as documentary review, which the Government Chemist has in fact carried out on occasion).

> Article 35
> 1. The competent authorities shall ensure that operators, whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls, have the right to a second expert opinion, at the operator's own expense.
> The right to a second expert opinion shall entitle the operator to request a documentary review of the sampling, analysis, test or diagnosis by another recognised and appropriately qualified expert.
> 2. Where relevant, appropriate and technically feasible, having regard in particular to the prevalence and distribution of the hazard in the animals or goods, to the perishability of the samples or the goods and to the amount of available substrate, the competent authorities shall:
> (a) when taking the sample, and if so requested by the operator, ensure that a sufficient quantity is taken to allow for a second expert opinion and for the review referred to in paragraph 3, should this prove necessary; or

(b) where it is not possible to take a sufficient quantity as referred to in point (a), inform the operator thereof.
This paragraph shall not apply when assessing the presence of quarantine pests in plants, plant products or other objects for the purpose of verifying compliance with the rules referred to in point (g) of Article 1(2).
3. Member States may decide that, where there is a dispute between the competent authorities and the operators that is based on the second expert opinion referred to in paragraph 1, the operators may request, at their own expense, the documentary review of the initial analysis, test or diagnosis and, where appropriate, another analysis, test or diagnosis by another official laboratory.
4. The application by the operator for a second expert opinion under paragraph 1 of this Article shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human, animal and plant health, or to animal welfare or, as regards GMOs and plant protection products, also to the environment, in accordance with this Regulation and with the rules referred to in Article 1(2).

The writer's view is that the proposed Article 35 text is a useful extension of extant EU law in this area. The current UK Government Chemist arrangements for technical appeal (referee analysis) are likely to address the proposed requirements. Moreover with a long history of implementation, and tailored to UK circumstances, present UK arrangements may prove to be more streamlined and hence more effective. Further detail and a Q & A from the Commission is available.[284, 285]

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[286].

A useful review of food safety policy and regulation in the United States is available (dated 2015) from the European Commission.[287]

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.[288]

5.2 Community Reference Laboratories

See section 6.2, 'Feed Additives'.

[284] http://europa.eu/rapid/press-release_MEMO-17-611_en.htm
[285] https://ec.europa.eu/food/safety/official_controls/review_en
[286] https://www.fda.gov/Food/GuidanceRegulation/FSMA/
[287] 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
[288] http://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/regulatory-initiatives/sfca/consultation/eng/1426531180176/1426531265317

5.3 Expert Scientific Committees

In late March 2016 the FSA published the triennial review of six FSA Scientific Advisory Committees:

- The General Advisory Committee on Science (GACS)
- The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)
- The Advisory Committee on the Microbiological Safety of Food (ACMSF)
- The Advisory Committee on Animal Feedingstuffs (ACAF)
- The Advisory Committee on Novel Foods and Processes (ACNFP), and
- The Social Science Research Committee (SSRC).

Amongst the eight recommendations, the review concluded that the role of providing independent, high-level advice and challenge on the FSA's use of science should pass from the GACS to a new Science Council. This mirrors similar models in other Government departments.
It is 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 would be established by December 2017. The SSRC will work as an expert committee of the FSA, focusing on providing advice and challenge on how the FSA can use social sciences to deliver its strategic priorities. The ACMSF and COT will retain their current structure and function. 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. Further recommendations can be viewed in the full report.[289]

The FSA and its Chief Scientific Adviser advertised for applications to join the new independent FSA Science Council on 28 November 2016 with a closing date for applications of midnight on Monday 5 December 2016.[290]

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.[291] 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.[292] The Scottish Food and Feed Law Guide was published in December 2016.[293]

A revised Food Law Code of Practice for England was issued on 30 March 2017.[294]

5.5 Food law prosecutions database

In November 2015 the FSA announced[295] the publication of a food law prosecutions database. The database[296] gives details of local authority food hygiene and food safety prosecutions

[289] https://www.food.gov.uk/news-updates/news/2016/15022/triennial-review-of-six-fsa-scientific-advisory-committees
[290] https://www.food.gov.uk/news-updates/news/2016/15680/applications-open-for-new-independent-science-council
[291] https://www.food.gov.uk/enforcement/codes-of-practice/food-law-code-of-practice-2015
[292] https://www.food.gov.uk/sites/default/files/Food%20Law%20Practice%20Guidance%20October%202015%20-%20FINAL%20.pdf
[293] http://www.foodstandards.gov.scot/scottish-food-and-feed-law-guide
[294] https://www.food.gov.uk/enforcement/codes-of-practice/food-law-code-of-practice
[295] http://www.food.gov.uk/news-updates/news/2015/14644/food-standards-agency-publishes-food-law-prosecutions-database
[296] http://www.food.gov.uk/enforcement/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

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.[297]

5.7 Food Standards Scotland

The Food (Scotland) Act 2015[298] established Food Standards Scotland (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

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. The following recent surveillance amendments remain active: groundnuts and derived products originating from Madagascar (aflatoxins), palm oil from Ghana (Sudan dyes), lemons from Turkey (pesticides residues),[299] and hazelnuts originating from Georgia for aflatoxins.[300] In addition Commission Implementing Regulation (EU) 2016/2107[301] of 1 December 2016 added groundnuts and derived products originating from Bolivia (aflatoxins), sesamum seeds (*salmonella*) and aubergines (pesticides residues) from Uganda, pineapples from Benin (pesticides residues), table grapes from Egypt (pesticides residues) and pomegranates from Turkey (pesticides residues). Regulation (EU) 2016/2107 contains the current full list which, interestingly, contains an entry for enhanced checks on dried apricots for sulphites, the subject of several recent referee cases.

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 largely exceeding the acute reference dose tentatively established by EFSA were found and the prohibition which was to apply until 30 June 2016 was extended for another three years.[302]

Commission Implementing Regulation (EU) 2016/2106 of 1 December 2016 amended Implementing Regulation (EU) No 884/2014 which imposes special conditions on the import of certain feed and food from certain third countries due to contamination risk by aflatoxins. Regulation (EU) 2016/2106 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.[303]

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[297] https://www.food.gov.uk/news-updates/news/2016/15747/fsa-publishes-local-authority-food-law-enforcement-information
[298] http://www.legislation.gov.uk/asp/2015/1/pdfs/asp_20150001_en.pdf
[299] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1466699635302&uri=CELEX:32016R0443
[300] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1024&rid=214
[301] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.327.01.0050.01.ENG&toc=OJ:L:2016:327:TOC
[302] 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
[303] 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

5.9 Local authority enforcement activity

No centrally published new updates were published in the quarter. We remain open to including in this review any updates communicated by individual local authorities to the author. However see 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 published on 9 December 2016 its annual report on progress towards implementation of the UK Multi-Annual National Control Plan. The report informs the European Commission on progress in achieving the objectives of the plan, summarises the results of official controls and associated activities carried out by the competent authorities and associated bodies, and outlines the findings of performance audits.[304]

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.[305] The FSA has invited[306] recommendations for priorities for the 2016-17 National Coordinated Sampling Programme which were published in September 2016.[307]

On 29 November 2016 the FSA held a 'Food Surveillance Summit' as part of the development phase for a new food surveillance approach.[308]

5.12 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.[309] RDNA appears to be a useful mechanism of clarifying regulatory need and seems to be open to all stakeholders.[310] 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.[311]

5.13 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

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304 https://www.food.gov.uk/news-updates/news/2016/15807/2015-annual-report-on-uk-multi-annual-national-control-plan-published
305 https://www.food.gov.uk/enforcement/sampling/samplingandsurveillance
306 https://www.food.gov.uk/news-updates/help-shape-our-policies/priorities-for-the-2016-17-national-coordinated-sampling-programme
307 https://www.food.gov.uk/sites/default/files/food-sampling-guidance-2016-17.pdf
308 https://www.food.gov.uk/news-updates/news/2016/15753/food-surveillance-summit-get-involved
309 https://www.gov.uk/government/news/fresh-food?mc_cid=127fb196ca&mc_eid=f1b5809dbc
310 http://rdna-tool.bis.gov.uk/
311 http://www.regulatorsdevelopment.info/grip/food

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.[312]

5.14 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 2074/2005[313] 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.

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

[312] 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

[313] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1494594527755&uri=CELEX:02005R2074-20160603

deals with the execution and enforcement of Regulation 183/2005, which provides that almost all businesses producing, trading in or using animal feed should be either registered, or approved, by the competent authorities.

The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015[314] (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.

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 2016[315] (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) 2016[316] (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).

6.1.1 Mycotoxin recommended limits

Commission Recommendation (EU) 2016/1319[317] of 29 July 2016 amended Recommendation 2006/576/EC as regards deoxynivalenol, zearalenone and ochratoxin A in pet food. Commission

[314] http://www.legislation.gov.uk/uksi/2015/255/pdfs/uksi_20150255_en.pdf
[315] http://www.legislation.gov.uk/nisr/2016/4/pdfs/nisr_20160004_en.pdf
[316] http://www.legislation.gov.uk/nisr/2016/5/pdfs/nisr_20160005_en.pdf

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.

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. Commission Regulation 2015/1905[318] amended Annex II to regulation 183/2005 as regards the dioxin testing of oils, fats and derived products.

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 askes Member States to monitor for the presence of nickel in feed.[319]

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 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.[320]

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.[321]

In May 2016 the EFSA Panel on Additives and Products or Substances used in Animal Feed, FEEDAP, reviewed a series of guidance documents intended to help applicants in their

[317] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016H1319
[318] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.278.01.0005.01.ENG
[319] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1471533458929&uri=CELEX:32016H1110
[320] 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
[321] http://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register/index_en.htm

preparation of technical dossiers, listed those that remain relevant and identified those that will need to be revised.[322]

The Official Journal L 13 English edition Volume 60 of 17 January 2017 included 14 Commission Implementing Regulations authorising over 200 substances as feed additives following re-evaluation by EFSA.[323]

The Animal Feed (Scotland) Amendment Regulations 2017 No. 38[324], 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. Regulation 2 re-states the definition of "Regulation 1831/2003" so that it includes all amendments made to it up to and including Commission Regulation (EU) 2015/2294. The definition therefore includes the amendments made by Commission Regulation (EU) 2015/327.

6.2.1 Community and National Reference Laboratories

Regulation (EC) No 1831/2003 deals with application for, and authorisation of, feed additives in animal nutrition with detailed rules in Regulation (EC) No 1831/2003 including the duties and tasks of the Community Reference Laboratory (CRL). In October 2015 Commission Implementing Regulation 2015/1761[325] 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.[326] 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.[327]

7 Acknowledgements

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[322] http://www.efsa.europa.eu/en/efsajournal/pub/4473
[323] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:013:TOC
[324] http://www.legislation.gov.uk/ssi/2017/38/contents/made
[325] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.257.01.0030.01.ENG
[326] 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
[327] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1618