



Food and feed law:

**Compendium of UK food and feed legislation
with associated context and changes during
July – September 2018**

Government Chemist Programme Report



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Business, Energy
& Industrial Strategy

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UK food and feed legislation & changes during July to September 2018

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Introduction to 'Food and feed law' review series

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

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

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

Please note – key information to maintain a permanent introduction to relevant legislation in certain areas is carried forward from previous reports, however legislation in force and made prior to July 2018 may not necessarily be reiterated herein. No responsibility can be taken for the use made of any view, information or advice given. In particular, any view, information or advice given should not be taken as an authoritative statement or interpretation of the law, as this is a matter for the courts.

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

The sources of information used have been Office of Public Sector Information ([OPSI](#)), Food Standards Agency ([FSA](#)) updates, European Food Safety Authority ([EFSA](#)) and the European legislative information database, [EUR-Lex](#). Extensive use has been made of the explanatory notes and recitals that accompany legislation. Hyperlinks in the document were accessed and available at the date of this report. The reports are not indexed but the Table of Contents is extensive.

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

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

Summary

The summary updates our legislation review with developments in food and feed law and related scientific and regulatory issues for the period from July to September 2018. Cross-cutting issues are mentioned first followed by technical updates in alphabetical order by subject. For further information and references to original sources please see the relevant section of the main report.

Cross-cutting issues

Exiting the EU

Political developments continued in the period and the Department for Exiting the European Union's rolling list of events and policy website was regularly updated.

The most significant legislation in the quarter was the European Union (Withdrawal) Act 2018 which received Royal Assent on 26 June 2018. This is an Act to repeal the European Communities Act 1972 and make other provision in connection with the withdrawal of the United Kingdom from the EU. The Act ends the supremacy of European Union (EU) law in UK law, converts EU law as it stands at the moment of exit into domestic law, and preserves laws made in the UK to implement EU obligations. It creates temporary powers to make secondary legislation to enable corrections to be made to the laws that would otherwise no longer operate appropriately once the UK has left the EU, so that the domestic legal system continues to function correctly. The Act also enables domestic law to reflect the content of a withdrawal agreement under Article 50 of the Treaty on European Union once the UK leaves the EU, subject to the prior enactment of a statute by Parliament approving the final terms of withdrawal. Thus the principal purpose of the Act is to provide a functioning statute book on the day the UK leaves the EU. As a general rule, the same rules and laws will apply on the day after exit as on the day before. It will then be for Parliament and, where appropriate, the devolved legislatures to make any future changes. Thus any policy changes will await separate primary legislation after withdrawal. Any UK measure passed after exit day that is in conflict with existing EU law will take precedence over 'converted' EU law.

Decisions of the Court of Justice of the EU (CJEU) made after exit day will not be binding on UK courts and cases cannot be escalated to the CJEU. However UK courts can have regard to actions of the EU post-exit including CJEU decisions, as they might to relevant decisions in higher courts in Commonwealth countries and other jurisdictions. Any question as to the meaning of unmodified retained EU law will be determined in UK courts in accordance with relevant pre-exit CJEU case law and general principles. Lower UK courts remain bound by pre-exit-day CJEU decisions but the Supreme Court and its equivalent in Scotland, the High Court of Justiciary, are not bound by either retained general principles or retained CJEU case law. (See Section 1.1)

Codex Alimentarius

A new 2018 publication, 'Understanding Codex' is a valuable guide to its operation. Other Codex activity in the period July – September 2018 included a tool to track new Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) measures. (See Section 1.2)

Consumer attitudes

The FSA publishes regular reports of surveys into information about the public's self-reported behaviours, attitudes and knowledge relating to food issues. The latest such report, published on 1 August 2018 showed the top food safety issues of concern for respondents were:

- Food hygiene when eating out (33%)

- Chemicals from the environment, such as lead, in food (30%)
- Food additives (29%)
- Food poisoning (28%)

(See Section 3.7)

Technical updates

Animal welfare

The Code of Practice (CoP) for the Welfare of Laying Hens and Pullets came into effect on 8 August 2018 revoking the previous CoP. The CoP provides updated and improved guidance on how to comply with the relevant farm animal welfare legislation and how to practise good standards of stockmanship to help enhance the welfare of their animals.

The Court of Justice of the European Union, CJEU, gave a preliminary ruling on the protection of animals at the time of killing. The referral to the CJEU was made in proceedings between various Muslim associations and umbrella organisations of mosques active in the Vlaams Gewest (Flemish Region, Belgium) concerning the decision adopted by a Flemish Government Minister no longer to authorise, from 2015 onwards, the ritual slaughter of animals without stunning in temporary slaughterhouses in the communes of that region during the Muslim Feast of Sacrifice. The ruling rehearses the relevant law and circumstances, including those of slaughter, confirmed the validity of certain questioned articles of law and noted that these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court. (See Section 3.1.1)

Common organisation of the markets in agricultural products

Regulation (EU) No 1308/2013 establishes a common organisation of the markets in agricultural products and is an extensive piece of legislation that covers many commodity sectors. Commission Implementing Regulation (EU) 2018/1146 of 7 June 2018 made various amendments to subsidiary legislation including on categories of grapevine products, oenological practices (e.g. increases in the natural alcoholic strength by volume) and the applicable restrictions. (See Section 3.3.7)

Feed additives

Feed additive authorisations are not routinely reported herein however an interesting example arose of denial of authorisation of riboflavin (vitamin B₂) produced by a strain of *Bacillus subtilis* as a feed additive. The additive is produced by a genetically modified strain and, based on information supplied by the applicant company, EFSA concluded that neither the production strain nor its recombinant DNA would be detected in the final product. However, a national competent authority laboratory, using a developed PCR assay detected the presence of viable cells and of recombinant DNA from the production strain in some reference samples of the additive. Consequently, although the applicant contested the laboratory method, EFSA reviewed the results and the Commission denied the authorisation. (See Section 6.4)

Food Authenticity

Databases of DNA sequence information are frequently used to assess food authenticity. However the verification and curation of the uploaded data must of course itself be authentic. This can depend on the taxonomic assignment of the specimen from which the original sequence was derived hence a database of morphological descriptors is essential to help avoid initial taxonomic misclassification. A useful source which was updated in September 2018 is the

'Catalog of Fishes', giving morphological characteristics in aid of field identification of specimens. (See Section 1.7)

Food flavourings

Commission Regulation (EU) 2018/1246¹ of 18 September 2018 amended Annex I to Regulation (EC) No 1334/2008 to allow inclusion of pyroligneous distillate (FL no. 21.001, 'rum ether') in the EU list of flavourings. This is a complex mixture of more than eighty individual constituents and the presence of genotoxic substances is of safety concern, e.g. furans and other constituents associated with genotoxicity and carcinogenicity. However the Czech and the Slovak Republics asked the Commission to retain use of pyroligneous distillate in the traditional spirit drinks *tuzemák* and *tuzemský*.

Commission Regulation (EU) 2018/1259 of 20 September 2018 allowed products already on the market or labelled prior to 22 April 2010 and containing the flavouring 'grill flavour concentrate (vegetable)' to be sold until the end of their date of minimum durability or use-by-date. The application for the approval of the flavouring had been received two days before the expiry date for applications (22 October 2015) and a transition period was deemed appropriate while studies requested by EFSA are completed. (See Section 2.4.11)

Food hygiene

Commission Implementing Decision (EU) 2018/935 of 28 June 2018 continued the temporary suspension of imports from Bangladesh of Betel leaves, following a high number of notifications issued to the Rapid Alert System for Food and Feed (RASFF) of a wide range of *Salmonella* strains. Despite action by the authorities in Bangladesh the situation has not improved sufficiently and the ban is continued until 30 June 2020. (See Section 2.15)

Genome editing

A significant case concerning genome editing before the Court of Justice of the European Union, CJEU, on 25 July 2018 was reported in September 2018. The case centres on 'mutagenesis', which encompasses genome editing, and was referred for a preliminary ruling to the CJEU by a French national court hearing proceedings by a French agricultural union and eight NGOs (the applicants) against the French government. The proceedings concern government refusal to revoke French national legislation according to which organisms obtained by mutagenesis are not, in principle, considered to result in genetic modification, and the refusal to ban the cultivation and marketing of herbicide-tolerant rape varieties obtained by mutagenesis.

In summary, the CJEU held that organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive. However, organisms obtained by mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record are exempt from those obligations, on the understanding that the Member States are free to subject them, in compliance with EU law, to the obligations laid down by the GMO directive or to other obligations.

Genetically modified organisms

Five GM events were re-authorised in August 2018 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. The usual conditions were placed on the labelling and use. (See Section 3.4)

¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.235.01.0003.01.ENG&toc=OJ:L:2018:235:TOC#ntr5-L_2018235EN.01000301-E0005

Import controls

Commission Regulation (EC) No 669/2009 which lays down rules concerning the list of imports of feed and food of non-animal origin foods subject to increased level of official controls is frequently amended in the light of emerging evidence. In July 2018 the regulation was further amended to include goji berries from China for pesticides residues and of pickled turnips from Lebanon and from Syria for the illegal dye Rhodamine B. Several entries in the list were deleted and for other entries a decrease in the frequency of controls for pesticides residues was allowed. Consignments of okra attracted an increased level of official controls at Union borders. The existing entries on tea from China in the list required testing for the herbicide triflurarin. This is no longer required owing to reduced incidence, but is replaced with a requirement for testing for the insecticide tolfenpyrad. (See also 'Food Hygiene' above). (See Section 5.8)

Meat and processed meat

There has long been speculation on the carcinogenicity of red meat and processed meat. Carcinogens can be produced by cooking of meat, with greatest amounts generated at high temperatures by pan-frying, grilling, or barbecuing. Meat processing such as curing and smoking can result in formation of carcinogens. In August 2018 the International Agency for Research on Cancer (IARC) published a monograph attempting to summarise research to date on this topic. In this complex and difficult area definitive conclusions are difficult to arrive at. However based on the balance of evidence, an increased risk of cancer of the colorectum was seen in relation to consumption of red meat and of processed meat. The majority of well-designed, population-based case-control studies that reported on the association with consumption of processed meat, showed increased risks for gastric cancer. Positive associations between processed meat consumption and stomach cancer were observed in several case-control and cohort studies in diverse populations. However, the modest number of studies and lack of association in the other cohort studies suggested that chance, bias, and confounding could not be ruled out. (See Section 2.13.1)

Microplastics

The Environmental Protection (Microbeads) (Wales) Regulations 2018 were made on 19 June 2018 and came into force on 30 June 2018. These Regulations prohibit the use of microbeads as an ingredient in the manufacture of rinse-off personal care products and the sale of any such products containing microbeads. (See Section 1.15)

Novel Foods

Eight novel foods were authorised between July and September 2018.

1. Hen egg white lysozyme hydrolysate in food supplements.
2. An extension, owing to increased vitamin D, of use levels of UV-treated mushrooms. A maximum of 20 µg of vitamin D₂ per 100 g fresh weight is permitted.
3. An extension of use of UV-treated baker's yeast (also as a result of increased vitamin D) but only intended for baking and not to be eaten. Maxima for vitamin D₂ are given.
4. Oil from the micro algae *Schizochytrium* sp. Multiple applications had been received for extension from previously authorised strains of the micro algae to a different strain and extend its use to fruit and vegetable purees. The oil contains docosahexaenoic acid (DHA) an omega-3 fatty acid said to be important for health. Maximum use levels in a variety of foods and maximum DHA concentrations in supplements are given.
5. Pyrroloquinoline quinone disodium salt for use in food supplements to a maximum intake of 20 mg per day. The food supplement should be consumed by adults only, excluding pregnant and lactating women. Disodium pyrroloquinoline quinone has been studied as a compound with strong antioxidant capacity and for its effects on serum lipid levels.

6. 1-methylnicotinamide chloride as a novel food for use in food supplements to a maximum intake of 58 mg per day adults only, excluding pregnant and lactating women.
7. Dried aerial parts of *Hoodia parviflora* for use in food supplements to a maximum intake of 9.4 mg per day. The marketed form is the dried powdered whole aerial parts of *Hoodia parviflora* N.E.Br., (family *Apocynaceae*). Species of *Hoodia*, a southern African succulent plant, have been studied for their appetite suppressing properties.
8. The removal of the word 'synthetic' from the designation and specific labelling of the novel food previously authorised as 'synthetic zeaxanthin' was allowed.

In addition the use of the previously authorised novel food 'lactitol' was extended to powdered form in food supplements.

Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 updated the current EU list of novel foods under Implementing Regulation (EU) 2017/2470.

It is occasionally necessary to appraise a food product that purports to represent a traditional recipe possibly unfamiliar to a UK based analyst. In this regard a publication from the Food and Agriculture Organization, 'Recipe book: health, knowledge and flavours' may be of interest. The book is a compilation of 23 recipes used by women from 20 countries in Latin America and the Caribbean. (See Section 3.6)

Olive oil

Commission Delegated Regulation (EU) 2018/1096 of 22 May 2018 amended Implementing Regulation (EU) No 29/2012 as regards the requirements for certain indications on the labelling of olive oil. These indications included labelling of the acidity but only if peroxide value, waxes content and ultraviolet absorption are also indicated and values are the maximum expected by the date of minimum durability. Indication of the year of harvest is also permitted subject to certain rules. (See Section 3.3.11)

Organic food

Commission Implementing Regulation (EU) 2018/949² of 3 July 2018 amended Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 on imports of organic products from third countries. The new implementing regulation makes a series of changes to control bodies notified by a range of third countries. (See Section 3.1.6)

Pesticides residues

In a series of linked cases the General Court of the Court of Justice of the European Union confirmed the validity of the restrictions introduced at EU level in 2013 against the insecticides clothianidin, thiamethoxam and imidacloprid because of the risks those substances pose to bees. However, it largely upheld the action brought by BASF and annulled the measures restricting the use of the pesticide fipronil, since they were imposed without a prior impact assessment. (See Section 2.9)

Regulation

The Food and Feed (Miscellaneous Amendments and Revocations) (Wales) Regulations 2018 were made on 2 July 2018, (in force on 26 July 2018) to amend 27 statutory instruments and revoke a further 62. (See Section 5)

² https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.167.01.0003.01.ENG&toc=OJ:L:2018:167:TOC

Spirit Drinks

Commission Regulation (EU) 2018/1098³ of 2 August 2018 amended and corrected Annex III to Regulation (EC) No 110/2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks. The amendments generally concern non-UK spirit drinks however the entry 'Ireland' related to 'Irish Potteen/Irish Poitin' is clarified to cover the corresponding spirit drink produced in [the Republic of] Ireland and Northern Ireland.

The Court of Justice of the European Union gave a preliminary ruling on the interpretation of Regulation (EC) No 110/2008 on spirit drinks in relation to the registered geographical indication 'Scotch Whisky'. (See Section 3.3.13)

Statutory duties

Pursuant *inter alia* to Local Authority statutory duties, Judicial Reviews of a local authority decision to make significant cuts to the library service in Northamptonshire were decided by Mrs Justice Yip sitting in the High Court (Queen's Bench Division, Administrative Court). The Judgement, hinging as it does on the circumstances of the claimants and the decision trail of the local authority may or may not have any bearing on other statutory duties. (See Section 5.15)

Transmissible Spongiform Encephalopathies

Commission Regulation (EU) 2018/969 of 9 July 2018 amended Annex V to Regulation (EC) No 999/2001 on the requirements for the removal of specified risk materials (SRM) from small ruminants. SRM carries an increased risk of transmission of spongiform encephalopathies. The amendment, following a detailed risk assessment relaxed the rules as regards SRM in ovine and caprine animals.

The Transmissible Spongiform Encephalopathies (Wales) Regulations 2018⁴, made in September 2018 and in force from 1 October 2018 revoke and remake with amendments the Transmissible Spongiform Encephalopathies (Wales) Regulations 2008. They continue to enforce Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. (See Section 2.12)

³ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.197.01.0007.01.ENG&toc=OJ:L:2018:197:TOC

⁴ <https://www.legislation.gov.uk/wsi/2018/968/introduction/made>

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1 Cross-cutting issues

1.1 Exiting and new partnership with the European Union

Background information is at Section 1.1 of our previous reports.⁵⁻⁸ The Department for Exiting the European Union maintains a rolling list of events and policy.⁹ The European Commission also maintains a rolling list of events and papers.¹⁰

The most significant legislation in the quarter was the European Union (Withdrawal) Act 2018¹¹ which received Royal Assent on 26 June 2018. This is an Act to repeal the European Communities Act 1972 and make other provisions in connection with the withdrawal of the United Kingdom from the EU. The Act ends the supremacy of European Union (EU) law in UK law, converts EU law as it stands at the moment of exit into domestic law, and preserves laws made in the UK to implement EU obligations. It creates temporary powers to make secondary legislation to enable corrections to be made to the laws that would otherwise no longer operate appropriately once the UK has left the EU, so that the domestic legal system continues to function correctly. The Act also enables domestic law to reflect the content of a withdrawal agreement under Article 50 of the Treaty on European Union once the UK leaves the EU, subject to the prior enactment of a statute by Parliament approving the final terms of withdrawal. Thus the principal purpose of the Act is to provide a functioning statute book on the day the UK leaves the EU. As a general rule, the same rules and laws will apply on the day after exit as on the day before. It will then be for Parliament and, where appropriate, the devolved legislatures to make any future changes. Thus any policy changes will await separate primary legislation after withdrawal. Any UK measure passed after exit day that is in conflict with existing EU law will take precedence over 'converted' EU law.

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Explanatory Notes have been produced to assist in the understanding of this Act and are available separately.¹²

⁵ <https://www.gov.uk/government/publications/food-and-feed-law-update-january-march-2017>

⁶ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2017>

⁷ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-july-to-september-2017>

⁸ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-january-march-2018>

⁹ <https://www.gov.uk/government/policies/brexit>

¹⁰ https://ec.europa.eu/commission/brexit-negotiations_en

¹¹ European Union (Withdrawal) Act 2018 : 2018: Chapter 16, <http://www.legislation.gov.uk/ukpga/2018/16/contents>

¹² http://www.legislation.gov.uk/ukpga/2018/16/pdfs/ukpgaen_20180016_en.pdf

The European Union (Withdrawal) Act was brought into operation by the European Union (Withdrawal) Act 2018 (Commencement and Transitional Provisions) Regulations 2018.¹³ The 'first appointed day' is 4 July 2018 but the Act will only fully come into effect on exit day. The provisions include definitions of certain EU-exit related terms like "retained EU law", and powers to prevent challenges to retained EU law post-exit on the grounds that an EU instrument was invalid.

Devolved legislation is dealt with, with the power to repeal restrictions on devolved competence in any retained EU law and create the duty to review whether it is appropriate to repeal those provisions or revoke any regulations made under those provisions. The Act allows a Minister of the Crown to make directions as to which matters are to be exempted from the general duty on the Queen's Printer to publish the relevant EU instruments and Treaties that were in force immediately before exit day. A Minister of the Crown may also make regulations about judicial notice and the admissibility of specified evidence of matters relating to retained EU law, EU law, the EEA agreement and other instruments or documents issued by an EU entity. It is made clear that the Act does not (a) prevent the UK from mirroring EU law in domestic law after exit day or (b) prevent the UK from continuing to participate in (or have other types of ongoing relationship with) EU agencies after exit day.

Various consequential provisions (contained in Schedule 8 of the Act) amend the Interpretation Act 1978.

The Commencement and Transitional Provisions regulation also brings into force the repeal of certain Acts listed in Schedule 9 of the Bill (none of which appear food or feed related) to the extent specified, and the repeal of the European Union Act 2011 (c. 12) on exit day to the extent that the repeal has not already been commenced by the Withdrawal Act.

The European Communities (Designation Orders) (Revocation) (EU Exit) Regulations 2018¹⁴ were made in September 2018, in force on exit day, and are a consequence of the repeal of the European Communities Act 1972 by section 1 of the European Union (Withdrawal) Act 2018. They revoke the Orders in Council made under section 2(2) of the European Communities Act 1972, ECA, by which Ministers or departments were designated in relation to different subject matter areas for the purposes of implementing EU law. After the repeal of the ECA the UK will no longer implement obligations under the EU Treaties via the ECA and will therefore not require the orders which designate authorities to use the power in section 2(2) of the ECA. The Regulations also revoke the designation in Article 6 of the Transfer of Functions (Equality) Order 2007 (S.I. 2007/2914).

The European Union (Definition of Treaties Orders) (Revocation) (EU Exit) Regulations 2018¹⁵ were made in September 2018 in consequence of the repeal of the European Communities Act 1972 (c. 68) (the "ECA 1972") by section 1 of the European Union (Withdrawal) Act 2018 (c.16). They revoke the Orders in Council listed in their Schedule, all of which were made under section 1(3) of the ECA 1972 and which provided for the treaties, international agreements or other relevant texts that they specify to be regarded as EU Treaties as defined by section 1(2) of the ECA 1972.

¹³ <http://www.legislation.gov.uk/ukxi/2018/808/note/made>

¹⁴ <https://www.legislation.gov.uk/ukxi/2018/1011/contents/made>

¹⁵ <http://www.legislation.gov.uk/ukxi/2018/1012/introduction/made>

Legislative ramifications of the United Kingdom's Article 50 (Treaty on European Union) notification to leave the EU are collected here rather than in the subject-specific sections of this report.

1.1.1 Food law

On 1 February 2018 the Commission published a notice to stakeholders on the withdrawal of the UK and EU food law.¹⁶ The document notes that unless a ratified withdrawal agreement establishes another date, all EU primary and secondary law will cease to apply to the United Kingdom from 30 March 2019, 00:00 hrs (CET). The UK will then become a 'third country'. There is no reference to the avowed intention of the UK to transpose extant EU law into UK law on the same date. A partial synopsis of the document follows but the document itself should be considered by potentially affected parties and it should be noted that the impacts will most likely alter in the light of an agreement between the UK and the EU on withdrawal.

Commenting on food labelling, food information, and health or identification marks the document lists the relevant EU measures and suggests some changes that may be required in the labelling of UK products. For example:

- Mandatory origin of a food product, where the labelling refers to EU or non-EU;
- Labelling of the name/business name and address of the EU-27 importer of food from the UK;
- Health or identification marks according to Article 5 of Regulation (EC) No 853/2004. As of the withdrawal date these marks shall no longer include the "EC" abbreviation which is reserved for establishments located in the EU, but shall only include the name of the country (in full or with the ISO two-letter code) where the establishment is located.

The document lists the measures on food ingredients, food composition, contaminants and residue limits and food contact material for which continued compliance must be achieved to be marketed within the EU. It also discusses, with examples, requirements for food business operators and authorisation holders, or their representatives, to be established in the EU and submission of authorisation requests through an EU member state.

EU food law sets rules for food production, food hygiene, food irradiation and organic production which must be followed if this food is to be placed on the EU market. EU food law also provides for specific controls upon entry of food into the EU.

As of the withdrawal date, the importation of food of animal origin from the United Kingdom into the EU-27 will be prohibited, unless certain listed requirements are met.

The importation of food of non-animal origin into the EU is not subject to listing requirements of third countries and establishments. However EU Member States will carry out regular official controls on imported food of non-animal origin.

1.1.2 UK European Reference Laboratory designations removed

As a consequence of the United Kingdom notification in accordance with Article 50 of the Treaty on European Union a series of Regulations set out to remove the designations of certain UK laboratories as EU reference laboratories (EURLs). Background details on the duties of EU

¹⁶ https://ec.europa.eu/food/sites/food/files/notice_brexit_eu_food_law.pdf

Reference Laboratories are in Section 5.2 and further details of the changes are at Section 1.1.2 of our report on legislative changes in April to June 2018.¹⁷

1.1.3 Evaluation of plant protection products

The re-allocation of UK responsibility for evaluation of active substances in plant protection products to other Member States is covered in Section 1.1.3 of our report on legislative changes in April to June 2018.¹⁸

1.1.4 Parliamentary Office of Science and Technology

A Parliamentary Office of Science and Technology POSTNote, published in January 2018 on current UK trade in food and animal feed, examines the challenges raised to the security of UK food supply by withdrawal from the EU and analyses the policy options available for improving UK food security. It notes that nearly half of the food consumed in the UK is imported, mostly from the EU. Leaving the EU means that the Government will have to secure new agreements to maintain a diversity of markets for food trade and a ready supply of labour. Intentions for a new agriculture policy were announced in the Queen's Speech to replace the Common Agricultural Policy (CAP) and make decisions on farming subsidies. Policy options for maintaining UK food security include increasing UK productivity and diversifying production and changing consumption patterns, reducing food waste and ensuring equitable distribution of food.¹⁹

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.²⁰

A 2018 publication, 'Understanding Codex'²¹ is a valuable guide to its operation. The core function of Codex is the development of international standards. Details of Codex meetings and reports are available on the website.²²

Codex activity can be accessed on the 'News and Events' section of the Codex website.²³ Activity in the period July – September 2018 included a tool to track new Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) measures. The high volumes (e.g. more than 4 000 SPS and TBT notifications in 2017), present a challenge for stakeholders to track, filter and provide feedback on notifications of interest in a timely manner. To address this an alert system, ePing, was launched in November 2016. Once registered on the publicly available [ePing website](#) with their filter preferences, users start receiving email alerts when notifications affecting products or markets of particular interest to them are circulated. In addition, the ePing website can serve as a communication platform to exchange comments and other documentation (such as translations) related to notifications.²⁴

¹⁷ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-june-2018>

¹⁸ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-june-2018>

¹⁹ <http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN-0556>

²⁰ <http://www.fao.org/fao-who-codexalimentarius/home/en/>

²¹ <http://www.fao.org/fao-who-codexalimentarius/news-and-events/news-details/en/c/1152769/>

²² <http://www.fao.org/fao-who-codexalimentarius/meetings-reports/en/>

²³ [http://www.fao.org/fao-who-codexalimentarius/news-and-events/en/?page=2&ipp=10&tx_dynalist_pi1\[par\]=YToxOntzOjE6lkwiO3M6MToiMCI7fQ==](http://www.fao.org/fao-who-codexalimentarius/news-and-events/en/?page=2&ipp=10&tx_dynalist_pi1[par]=YToxOntzOjE6lkwiO3M6MToiMCI7fQ==)

²⁴ <http://www.fao.org/fao-who-codexalimentarius/news-and-events/news-details/en/c/1154073/>

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

The FSA published on 19 July 2017 a key paper²⁵ on the fundamental redesign of the FSA’s regulatory role and of the way in which regulation is delivered. The paper details the changes the FSA wants to make including:

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

Background to RoF is in Section 1.3 of our April to June report.²⁶

In December 2017 a proposal was announced in a paper endorsed by the FSA Board on surveillance strategy for formal review of the UK official control laboratory system in its entirety, to include the role of the Laboratory of the Government Chemist as the UK referee laboratory for food and feed. For reference the relevant text of the Board paper reads as follows.²⁷

6. Laboratories

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

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

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

6.4. Since the creation of the FSA there has never been a formal external review of the UK official control laboratory system in its entirety, encompassing the roles of public analysts, food examiners, agricultural analysts, national

²⁵ https://www.food.gov.uk/sites/default/files/media/document/rof-paper-july2017_0.pdf

²⁶ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2017>

²⁷ <https://www.food.gov.uk/about-us/our-board/meetings>

reference laboratories and the role of the Laboratory of the Government Chemist as the UK referee laboratory for food and feed. Over the years analytical techniques typically used for official control purposes have become more digital/instrumental in nature and there is no longer a clear demarcation between the current official control disciplines. In the build-up to the UK exiting the EU there is an opportunity to review the current system (taking into consideration, for example, capacity, capability, scale and surge, independence, competence, quality) such that the UK has a more joined-up, less-segmented, efficient and sustainable official control laboratory network thereby enabling the FSA to be an excellent, accountable, modern regulator.

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

A series of RoF newsletters is published by FSA.²⁸

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

Regulation (EC) No 882/2004 *on official controls* was replaced by Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 *on official controls and other official activities*.^{29, 30} Background to this was given in a previous edition of this report.³¹ Regulation 2017/625 supplements Regulation (EC) No 178/2002³² and, stemming from the Treaty on the Functioning of the European Union,³³ aims for a high level of:

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

A fuller discussion of Regulation (EU) 2017/625 is at Section 1.4 of our April to June 2017 report.³⁴

The European Commission website landing page³⁵ for Official Controls provides a useful summary of the main elements of the new regulation and a number of further links to background information including a Q&A.³⁶

1.5 Antimicrobial resistance, AMR

It has been estimated that the global impact of AMR could be 10 million deaths annually by 2050, and cost up to US \$100 trillion in cumulative lost economic output.³⁷ International action on AMR

²⁸ <https://www.food.gov.uk/about-us/regulating-our-future-newsletter>

²⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.095.01.0001.01.ENG&toc=OJ:L:2017:095:TOC

³⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1505320836050&uri=CELEX:02017R0625-20170407>

³¹ Walker M. J. (2017) Food and Feed Law: legislation review, January – March 2017, Section 5, pp 45 – 48, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/617645/Foodfeedlaw_Jan-Mar_2017_v3.pdf

³² Latest consolidated version at time of writing that of 30.06.2014: <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498146098818&uri=CELEX:02002R0178-20140630>

³³ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT>

³⁴ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2017>

³⁵ https://ec.europa.eu/food/safety/official_controls/legislation_en

³⁶ https://ec.europa.eu/food/sites/food/files/safety/docs/oc_qa_oregulation_20170407_en.pdf

³⁷ Prof Guy Poppy, FSA Chief Scientific Adviser's Science Report Issue four: Antimicrobial resistance in the food supply chain <https://www.food.gov.uk/sites/default/files/media/document/csa-amr-report.pdf>

is detailed on the European Commission website,³⁸ the UK Government website³⁹ and the World Health Organisation website.⁴⁰ See also Section 1.5 of our April to June 2018 report.⁴¹

1.6 Emerging risks

The Emerging Risks Exchange Network, EREN,⁴² has been referred to in previous reports^{43, 44} and regularly updates outline emerging risks in brief meeting reports.^{45, 46}

1.7 Food fraud/food crime

Food fraud is a dishonest act or omission in the production or supply of food intended for personal gain or to cause loss to another party. Food fraud becomes food crime when its scale is more complex or likely to be seriously detrimental to consumers, businesses or the overall public interest, or when organised criminals are involved. The criminal activity may be cross-regional, national or international. The concept of 'food crime' was highlighted by the Elliott Review which led to the establishment of the FSA's National Food Crime Unit,⁴⁷ NFCU.⁴⁸ Food Standards Scotland (FSS) independently established a Scottish Food Crime and Incidents Unit (SFCIU).⁴⁹

A crucial mechanism for coping with and mitigating the adverse effects of food fraud/crime is collation of intelligence. Food industry intelligence is often the most well-informed but must be carefully handled to avoid penalising the innocent 'whistle-blower'. A mechanism, the Food Industry Intelligence Network, FIIN, was established by 21 industry technical leaders to share intelligence on food authenticity.⁵⁰ FIIN membership in the UK includes major retailers, manufacturers and food service companies.⁵¹ Science and technology company Campden BRI was chosen to provide technical and administrative support to FIIN by curating a database to collect anonymised industry data on food authenticity testing. They will analyse the data producing regular reports for the FIIN members. Campden BRI will also be responsible for managing the FIIN membership and organising FIIN events.

In early 2016 the FSA published⁵² the first assessment of food crime in the UK, the Food Crime Annual Strategic Assessment (FCASA). Readers are referred to the FCASA for a list of strategic food crime priorities.

The United Nations Office on Drugs and Crime has published a 'World wildlife crime report 2016: Trafficking in protected species', which includes a case study on caviar in the seafood industry.⁵³ The report as a whole provides good background context for a topic in which molecular biology has a significant role to play.

³⁸ https://ec.europa.eu/health/amr/antimicrobial-resistance_en

³⁹ <https://www.gov.uk/government/collections/antimicrobial-resistance-amr-information-and-resources>

⁴⁰ <http://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance>

⁴¹ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-june-2018>

⁴² <http://www.efsa.europa.eu/en/cross-cutting-issues/networks>

⁴³ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-january-to-march-2016>

⁴⁴ <https://www.gov.uk/government/publications/food-and-feed-law-update-january-march-2017>

⁴⁵ https://www.efsa.europa.eu/sites/default/files/event/170503-m_1.pdf

⁴⁶ <http://www.efsa.europa.eu/sites/default/files/event/171122-1-m.pdf>

⁴⁷ <https://www.food.gov.uk/enforcement/the-national-food-crime-unit>

⁴⁸ <https://www.food.gov.uk/safety-hygiene/food-crime>

⁴⁹ <http://www.foodstandards.gov.scot/food-crime>

⁵⁰ <https://www.campdenbri.co.uk/news/fiin.php>

⁵¹ <https://www.campdenbri.co.uk/pr/food-fraud.php>

⁵² <https://www.food.gov.uk/sites/default/files/media/document/fsa-food-crime-assessment-2016.pdf>

⁵³ https://www.unodc.org/documents/data-and-analysis/wildlife/World_Wildlife_Crime_Report_2016_final.pdf

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 Commission⁵⁴ 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.⁵⁵ 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.⁵⁶

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.⁵⁷

Although not related to food, a recent report may be of interest because it measures the direct, economic effects of counterfeiting on (a) consumers, (b) retail and manufacturing industry and (c) governments in the United Kingdom. It covers the impact of fake products imported into the UK, and the impact of the global trade in fake products on UK intellectual property rights holders.⁵⁸

The authenticity of marine species often depends on the correct taxonomic identification of species for which DNA profiles are uploaded to public databases such as the Barcode of Life Data System (BOLD)⁵⁹ and the National Center for Biotechnology Information (NCBI) GenBank⁶⁰ hence we welcome the publication of 'Marine species biological data collection manual: an illustrated manual for collecting biological data at sea'.⁶¹

The JRC published monthly summaries on food fraud and adulteration⁶² and a great deal of up to date information is available on the Food Authenticity Network.⁶³

The Organisation for Economic Co-operation and Development (OECD) and The EU Intellectual Property Office (EUIPO) reviewed the misuse of free trade zones (FTZs) for trade in counterfeit and pirated goods. FTZs have a long role in world trade, dating back to at least the early 18th century. They can provide numerous, unequivocal benefits to business and host countries.

⁵⁴ http://ec.europa.eu/food/safety/official_controls/food_fraud/horse_meat/index_en.htm

⁵⁵ http://ec.europa.eu/food/safety/official_controls/food_fraud/index_en.htm

⁵⁶ <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm>

⁵⁷ 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

⁵⁸ <http://www.oecd.org/unitedkingdom/trade-in-counterfeit-products-and-the-uk-economy-9789264279063-en.htm>

⁵⁹ Ratnasingham, S. and Hebert, P.D.N. (2007) BOLD: The Barcode of Life Data System. Molecular Ecology Notes. <http://www.boldsystems.org/>

⁶⁰ National Center for Biotechnology Information, U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda MD, 20894 USA. <http://www.ncbi.nlm.nih.gov/>

⁶¹ <http://www.fao.org/3/a-i6353e.pdf>

⁶² <https://ec.europa.eu/jrc/en/food-fraud-and-quality/monthly-summary-articles>

⁶³ <http://www.foodauthenticity.uk/>

However, lightly regulated FTZs are also attractive to parties engaged in illegal and criminal activities, such as trade in counterfeit and pirated products or smuggling and money laundering, as these zones can offer a relatively safe environment with both good infrastructure and limited oversight. There is no reference to food fraud although there are clearly avenues where this might take place.⁶⁴

See also Section 3.3.5 on honey fraud detection and Section 3.1.3 for the Sea Fishing (Illegal, Unreported and Unregulated Fishing) Order (Northern Ireland) 2018.

Of passing interest to those with an interest in the horse meat incident may be the Equine Identification (England) Regulations 2018. These Regulations supplement, and make provision for the enforcement, of Commission Implementing Regulation (EU) 2015/262 in England. They provide for the identification of equine animals, and replace the Horse Passports Regulations 2009 (S.I. 2009/1611).⁶⁵

Databases of DNA sequence information such as the Barcode of Life Data System (BOLD) and the National Center for Biotechnology Information (NCBI) GenBank are frequently used to assess food authenticity. However the verification and curation of the uploaded data must of course itself be authentic. This can depend on the taxonomic assignment of the specimen from which the original sequence was derived hence a database of morphological descriptors is essential to help avoid initial taxonomic misclassification. A useful source which was updated in September 2018 is the 'Catalog of Fishes',⁶⁶ giving morphological characteristics in aid of field identification of specimens.

An annual anti-food fraud exercise, Operation OPSON, coordinated by Europol and INTERPOL is supported by customs, police and national food regulatory bodies in addition to partners from the private sector.⁶⁷

1.8 Incidents

The FSA decided to cease the production of the numbers of food incidents as an annual report in June 2017,⁶⁸ due to light demand for the statistics and difficulties in ensuring consistent categorisation. Instead, the underlying data is provided as open data on a monthly basis on the FSA website, although no analysis is provided.⁶⁹

1.9 Data science

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

⁶⁴ OECD/EUIPO (2018), Trade in Counterfeit Goods and Free Trade Zones: Evidence from Recent Trends, OECD Publishing, Paris/EUIPO. <http://dx.doi.org/10.1787/9789264289550-en>

⁶⁵ <http://www.legislation.gov.uk/ukxi/2018/761/note/made>

⁶⁶ Fricke, R., Eschmeyer, W. N. & R. van der Laan (eds) 2018. Catalog of Fishes: Genera, Species, References. <http://researcharchive.calacademy.org/research/ichthyology/catalog/fishcatmain.asp>

⁶⁷ <https://www.europol.europa.eu/operations/opson>

⁶⁸ <http://webarchive.nationalarchives.gov.uk/20180411170446/https://www.food.gov.uk/about-us/data-transparency-accounts/busreps/mischbusrep>

⁶⁹ <https://data.food.gov.uk/catalog/datasets>

In April 2017 FSA published⁷⁰ a report on data science from its Chief Scientific Adviser Professor Guy Poppy, his sixth Science Report. Advances in data science techniques are making the large amounts of data collected by the FSA and food businesses more valuable. The report shows how the Agency is bringing together a wide range of data, from the complex food industry ‘ecosystem’ to social media and consumer preferences, to explore ways that it can meet its regulatory responsibilities going forward and become data-driven. This also includes working in partnership on research with University College London’s Big Data Institute and the Office for National Statistics amongst others, to get the best value from data as well as supporting FSA objectives and learning with and from others. Data Science is feeding into the implementation of the Agency’s innovative new Surveillance Strategy and the ‘Regulating our Future’ change programme which is redesigning the FSA’s regulatory role.

A United Nations publication outlines a framework for integrated agri-food information management, taking into account the functional needs of various stakeholders along the supply chain. The benefits as well as challenges involved in developing a comprehensive system are discussed. Some examples of existing paperless systems – which are considered good practices for agri-food trade – are also included together with the list of relevant international standards to be taken into account when implementing the systems. Practical recommendations for, and milestones in the enhancement of agri-food information systems for trade facilitation are provided, including a recommendation to develop a Single Window for Agri-food Trade (SWAT). This publication is aimed mainly at government officials involved in overseeing and making policies related to agri-food trade. It is also relevant to the private sector (both existing and potential traders), associations and any agri-food supply-chain stakeholders interested in making agri-food trade both safer and more efficient. This policy guide builds on the series of technical and legal guides produced by UNNExT to facilitate paperless trade implementation.⁷¹ Previous guides are also available.⁷²

The Defra Food Statistics Pocketbook Summary was published in November 2017 and provides comprehensive economic and trend data on UK food.⁷³

1.10 Global data

Two useful compendia of data were published in late 2016: the World Bank ‘Little green data book 2016’⁷⁴ and the United Nations ‘World statistics pocketbook 2016’.⁷⁵ 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,

⁷⁰ <https://www.food.gov.uk/news-updates/news/2017/16129/science-report-published-on-use-of-data-science-in-the-fsa>

⁷¹ Information management in agrifood chains: towards an integrated paperless framework for agrifood trade facilitation
<http://unnex.unescap.org/pub/agriguide15.pdf>

⁷² <http://unnex.unescap.org>

⁷³ <https://www.gov.uk/government/statistics/food-statistics-pocketbook-2017>

⁷⁴ <http://data.worldbank.org/products/data-books/little-green-data-book>

⁷⁵ <http://unstats.un.org/unsd/publications/pocketbook>

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.⁷⁶

The United Nations published in January 2018 the 'World statistics pocketbook 2017', an annual compilation of key economic, social and environmental indicators, presented in one-page profiles. This edition includes profiles for the 30 world geographical regions and 232 countries or areas.⁷⁷

1.11 Machinery of government

An Order in Council⁷⁸ 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).

The Food and Drink Sector Council (FDSC)⁷⁹ which was announced in the BEIS Industrial Strategy white paper,⁸⁰ met for the first time on 29 January. The FDSC agreed priorities for the next 12 months, including a focus on boosting skills, enhancing agricultural productivity, improving the nation's nutrition and building on emerging proposals to establish a sector deal. The Council will set up expert working groups to develop recommendations for industry and government on each of its priorities.⁸¹

1.12 Food and Agriculture Organization, FAO

FAO is an intergovernmental organization present in over 130 countries. The Organization is comprised of 194 Member States, two associate members and one member organization – The European Union.⁸² FAO published in January 2018 'The state of food security and nutrition in the World 2017: building resilience for peace and food security'.⁸³ The summary to the publication explains that the 2030 Agenda for Sustainable Development and the UN Decade of Action on Nutrition 2016-2025 call on all countries and stakeholders to act together to end hunger and prevent all forms of malnutrition by 2030. This edition of 'The state of food security and nutrition in the world' marks the beginning of a regular monitoring of progress towards achieving the food security and nutrition targets set by the 2030 Agenda. In 2016 the number of chronically undernourished people in the world is estimated to have increased to 815 million, up from 777 million in 2015 although still down from about 900 million in 2000. After a prolonged decline, this recent increase could signal a reversal of trends. The food security situation has worsened, in particular in parts of sub-Saharan Africa, South-Eastern Asia and Western Asia, and deteriorations have been observed most notably in situations of conflict and conflict combined with droughts or floods. The apparent halt to declining hunger numbers is not yet reflected in the prevalence of child stunting, which continues to fall, though the pace of improvement is slower in some regions. Globally, the prevalence of stunting fell from 29.5 percent to 22.9 percent between

⁷⁶ [Common catalogue of varieties of agricultural plant species — 35th complete edition](#)

⁷⁷ <https://unstats.un.org/unsd/publications/pocketbook/files/world-stats-pocketbook-2017.pdf>

⁷⁸ 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

⁷⁹ <https://www.gov.uk/government/groups/food-and-drink-sector-council>

⁸⁰ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/664563/industrial-strategy-white-paper-web-ready-version.pdf

⁸¹ <https://www.gov.uk/government/news/food-and-drink-sector-council-meets-for-first-time>

⁸² <http://www.fao.org/home/en/>

⁸³ <http://www.fao.org/3/a-l7695e.pdf>

2005 and 2016, although 155 million children under five years of age across the world still suffer from stunted growth.

The publication goes on to cover wasting which affected one in twelve (52 million) of all children under five years of age in 2016, more than half of whom (27.6 million) live in Southern Asia. Multiple forms of malnutrition coexist, with countries experiencing simultaneously high rates of child undernutrition, anaemia among women, and adult obesity. Rising rates of overweight and obesity add to these concerns. Childhood overweight and obesity are increasing in most regions, and in all regions for adults. In 2016, 41 million children under five years of age were overweight. The number of conflicts is also on the rise. Exacerbated by climate-related shocks, conflicts seriously affect food security and are a cause of much of the recent increase in food insecurity. Conflict is a key driver of situations of severe food crisis and recently re-emerged famines, while hunger and undernutrition are significantly worse where conflicts are prolonged and institutional capacities weak. FAO calls for addressing food insecurity and malnutrition in conflict-affected situations. It requires a conflict-sensitive approach that aligns actions for immediate humanitarian assistance, long-term development and sustaining peace. FAO warn that the ambition of a world without hunger and malnutrition by 2030 will be challenging – achieving it will require renewed efforts through new ways of working.

In January 2018 FAO published 'Trade and food standards'.⁸⁴ This publication explains how international food safety standards are set through the Joint Food and Agriculture Organization of the United Nations and World Health Organization (FAO/WHO) Food Standards Programme – the Codex Alimentarius Commission – and how these standards are applied in the context of the World Trade Organization (WTO) Agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement).

In order to trade internationally and have access to markets for high-value products, producers must be able to meet national food regulations. Complying with these requirements in export markets can be challenging, especially for smaller producers in developing and emerging economies. The use of international food standards worldwide not only contributes to public health, but also helps reduce trade costs by making trade more transparent and efficient, allowing food to move more smoothly between markets. Through the FAO/WHO Codex Alimentarius, members establish science-based, internationally agreed food standards. These international standards are recognized by the SPS Agreement, thus becoming a benchmark for international trade in food products. The SPS Agreement lays down the rules for food safety, animal and plant health protection measures in trade, to ensure that such measures do not act as unnecessary barriers to trade. Members are increasingly also referring to Codex standards in the context of the TBT Agreement, which applies to other food regulations including quality and labelling requirements. The WTO also provides a set of tools to facilitate international dialogue on food-related measures, and to resolve trade concerns when they arise. The publication describes the two organisations, how they operate together, and how countries can and should engage to keep international food standards up to date and relevant, and to resolve trade issues. The publication also highlights the need to invest in domestic capacities to be prepared now and in the future to keep food safe and to ensure that trade flows smoothly. Coordination between all relevant agencies within government as well as with stakeholders from the entire food supply chain is essential. Actors with responsibility for food control systems require knowledge and skills. Investments in this area will allow a country to more effectively protect public health, contribute to shaping international standards and take advantage of trade opportunities. The publication also

⁸⁴ <http://www.fao.org/3/a-i7407e.pdf>

illustrates some of the drivers of change in the area of food regulation, underlining the need for governments to be constantly attentive and ready to pick up on challenges and new opportunities.

In September 2018 the UN Rotterdam Convention's Chemicals Review Committee held its 14th meeting at the Food and Agriculture Organization (FAO) Headquarters in Rome. Aimed to protect human health and the environment by assisting governments to make informed decisions concerning trade in pesticide and industrial chemicals, the meeting considered four hazardous chemicals:

- The pesticide acetochlor, used for example as a herbicide on maize, known to be highly toxic to aquatic organisms and posing a high risk to birds and non-targeted plants;
- The industrial chemical hexabromocyclododecane, used for example in flame retardants and polystyrene foam insulation, known to be carcinogenic, neurotoxic and harmful for human development as well as toxic to both aquatic and terrestrial species;
- The pesticide phorate, widely used to control insects on cotton, potatoes, coffee, beans and corn; and which is extremely toxic, causing lethality at low doses, and with studies showing poisonings and deaths amongst agricultural workers exposed to this active ingredient;
- The industrial chemical perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, widely used in domestic non-stick cooking ware and food-processing appliances, surface treatment agents in textiles, paper and paints, firefighting foams and is known to be toxic to humans and the environment with links to major health issues such as kidney cancer, testicular cancer, thyroid disease, and pregnancy-induced hypertension.

The decision to list these chemicals for international trade measures will be taken at subsequent Meetings of the Conference of the Parties (COPs), the next of which will be held in Geneva from 29 April to 10 May 2019.⁸⁵

1.13 The Transatlantic Trade and Investment Partnership (TTIP)

Background to TTIP is available on the European Commission's website.⁸⁶ In July 2017 the European Parliament published a resolution giving detailed recommendations to the Commission on TTIP.⁸⁷

1.14 Control of mercury

The Control of Mercury (Enforcement) Regulations 2017⁸⁸ were made in December 2017, coming into force on 1 January 2018, except Parts 2 and 3 which come into force on 1 April 2018. The regulations designate competent authorities (The Environment Agency, Northern Ireland Department of Agriculture, Environment and Rural Affairs, the Scottish Environment Protection Agency and the Natural Resources Body for Wales, in their respective jurisdictions) and sets offences and penalties. The regulations provide for the enforcement of Regulation (EU) 2017/852 on Mercury, adopted to fill gaps in existing EU mercury legislation and enable ratification of the Minamata Convention on Mercury. This Convention is designed to protect global human health and the environment from the adverse effects of exposure to mercury and includes restrictions on

⁸⁵ <http://www.fao.org/news/story/en/item/1152577/icode/>

⁸⁶ <http://ec.europa.eu/trade/policy/in-focus/ttip/>

⁸⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.265.01.0035.01.ENG&toc=OJ:C:2017:265:TOC

⁸⁸ <http://www.legislation.gov.uk/uksi/2017/1200/introduction/made>

the import and export of mercury, requirements for the phasing out of the use of mercury in a number of products and processes, as well as measures on interim storage of mercury and its disposal once it becomes waste.

See also Section 2.9 for data on environmental concentrations of mercury in various foods.

1.15 Microplastics

The prohibition in December 2017 in England of the use of microbeads in rinse-off personal care products was well-publicised. Public Analysts may be called upon to comment on what constitutes a 'microbead' thus it is noted that the Environmental Protection (Microbeads) (England) Regulations 2017 defines a 'microbead' as any water-insoluble solid plastic particle of less than or equal to 5 mm in any dimension.⁸⁹

FAO have published a literature review of microplastics in fisheries and aquaculture. The review finds that inadequate management of plastic waste has led to increased contamination of freshwater, estuarine and marine environments. It has been estimated that in 2010 between 4.8 million to 12.7 million tonnes of plastic waste entered the oceans. Abandoned, lost or otherwise discarded fishing gears are considered the main source of plastic waste by the fisheries and aquaculture sectors, but their relative contribution is not well known at regional and global levels. Adverse effects of microplastics ingestion have only been observed in aquatic organisms under laboratory conditions, usually at very high exposure concentrations that exceed present environmental concentrations by several orders of magnitude. In wild aquatic organisms microplastics have only been observed within the gastrointestinal tract, usually in small numbers, and at present there is no evidence that microplastics ingestion has negative effects on populations of wild and farmed aquatic organisms. Microplastic contamination of aquatic environments will continue to increase in the foreseeable future and at present there are significant knowledge gaps on the occurrence in aquatic environments and organisms of the smaller sized microplastics (less than 150 µm), and their possible effects on seafood safety. Currently there are no methods available for the observation and quantification of nanoplastics in aquatic environments and organisms. The review concludes that in humans the risk of microplastic ingestion is reduced by the removal of the gastrointestinal tract in most species of seafood consumed. However, most species of bivalves and several species of small fish are consumed whole, which may lead to microplastic exposure. A worst case estimate of exposure to microplastics after consumption of a portion of mussels (225 g) would lead to ingestion of 7 micrograms (µg) of plastic, which would have a negligible effect (less than 0.1 percent of total dietary intake) on chemical exposure to certain persistent, bioaccumulative and toxic contaminants (PBTs) and plastic additives.⁹⁰

The Environmental Protection (Microbeads) (Wales) Regulations 2018 were made on 19 June 2018 and came into force on 30 June 2018.⁹¹ These Regulations prohibit the use of microbeads as an ingredient in the manufacture of rinse-off personal care products and the sale of any such products containing microbeads (Regulation 3). A civil sanctions regime is also introduced to enable the regulator to impose a range of civil sanctions. These include variable monetary penalties, compliance notices and stop notices. The regulator may also accept enforcement undertakings. The Regulations make provision for the procedure relating to these sanctions and

⁸⁹ <http://www.legislation.gov.uk/ukxi/2017/1312/contents/made>

⁹⁰ Microplastics in fisheries and aquaculture: status of knowledge on their occurrence and implications for aquatic organisms and food safety, <http://www.fao.org/3/a-i7677e.pdf>

⁹¹ <http://www.legislation.gov.uk/wsi/2018/760/contents/made>

the available appeal mechanisms. Failure to comply with a stop notice is an offence. All appeals relating to a civil sanction are to the First-tier Tribunal. The regulations also provide for publication of information on enforcement action taken by the regulator, and that guidance relating to the use of civil sanctions must be prepared and consulted on and specify information to be included in such guidance. Regulators are able to recover the costs of enforcement in the case of variable monetary penalties, compliance notices and stop notices.

1.16 Metrology

Metrology is the science of measurement. The statutory and advisory functions of the Government Chemist benefit greatly by collocation with the UK National Measurement Laboratory (NML).⁹² The NML, designated for chemical and bio-measurement, has established itself as one of the top measurement institutes worldwide. It forms part of the UK National Measurement System (NMS), a consortium of laboratories funded by BEIS that provides the core measurement infrastructure for the UK.⁹³ The aims of the NML are twofold: (a) ensuring trust and confidence in chemical and bio-measurements in the UK as identified by government strategy and industry needs and (b) addressing measurement challenges of the future to foster innovation, promoting productivity and economic growth. NML research spans advanced therapeutics, diagnostics, safety and security, including food, and encompasses pure measurement research, calibration, reference materials and training and consultancy. The NML also sits within the international metrology community, supporting global consistency and traceability of measurement through its activities under the auspices of the International Bureau of Weights and Measures (BIPM), the organisation that maintains a coherent system of units. The European Association of National Metrology Institutes (EURAMET) is the Regional Metrology Organisation of Europe. Its mission is to develop and disseminate an integrated, cost effective and internationally competitive measurement infrastructure for Europe, taking into account the needs of industry, business and governments. Two main tools to achieve these goals are the European Metrology Research Programme (EMRP) and the European Metrology Programme for Innovation and Research (EMPIR).⁹⁴

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.⁹⁵⁻⁹⁸

Official risk management of food allergy depends mainly on food labelling. Food ingredients that may trigger food allergy (priority major allergens) or hypersensitivity reactions (gluten and sulfites) are specified in Annex II to Regulation 1169/2011 (the 'Food Information to Consumers Regulation', see Section 3.1 for a fuller discussion of this labelling regulation). If included in a

⁹² <https://www.lgcgroup.com/our-science/national-measurement-laboratory/#.W-Ac97p2vIW>

⁹³ <https://www.gov.uk/government/publications/national-measurement-system/uk-national-measurement-system>

⁹⁴ <https://www.euramet.org/about-euramet/>

⁹⁵ 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

⁹⁶ 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

⁹⁷ 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

⁹⁸ 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

prepacked foodstuff the designated ingredients must be emphasized, for example in **bold print** in the list of ingredients. Disclosure provisions also apply to Annex II foods in prepacked items that are not required to bear a list of ingredients and food sold non-prepacked. The global standard for food allergen labelling is that of the *Codex Alimentarius*.⁹⁹ However, unintended allergens, which might cross contaminate the supply chain during harvest, transport, storage or processing, are treated differently. Food business operators must implement a risk assessment in order to establish whether a hazard is likely to occur, and seek to either eliminate this risk, or reduce the risk of contamination to acceptable levels below which only the most sensitive allergenic subject might react. Advisory (“may contain ...”) labelling is often used but should only be applied when there is a demonstrable and significant risk of allergen contamination. Risk assessment approaches have been developed by the Allergen Bureau Voluntary Incidental Trace Allergen Labelling, VITAL® and the Integrated Approaches to Food Allergen and Allergy Management (iFAAM) consortium to manage food allergen risk. These apply milligram per kilogram allergen protein ‘action levels’ derived from the estimated eliciting dose extrapolated from dose-distribution relationships for the allergen and the food serving size. The eliciting dose is the predicted amount of allergenic food that may provoke an allergic reaction in a given percent of the population.

In December 2017 the Commission published a Notice¹⁰⁰ dated 13 July 2017 under document number 2017/C 428/01 giving further guidance on Annex II to Regulation 1169/2011. The guidance deals with ways of providing allergen information for pre-packed foods, both when the food bears or does not bear a list of ingredients, labelling of the same allergen derived from several ingredients or processing aids, exemptions when the name of the food clearly refers to the substance or product concerned, voluntary repetition, and updating of Annex II.

The convicted owner of the restaurant which caused the death of Paul Wilson appealed his conviction and sentence. The case was heard before Lord Justice Hickinbottom, Mr Justice Openshaw and His Honour Judge Topolski QC (sitting as a Judge of the Court of Appeal (Criminal Division)) on 12 October 2017. Grounds of appeal were (a) the judge’s directions to the jury on a number of issues including on ‘breach of duty’, ‘proof of legal causation’, ‘standard of care owed by the Appellant to customers’, ‘standard of proof and vicarious liability’, ‘foreseeability and risk of death’, ‘truthfulness of the appellant’, and (b) the sentence (six years) was manifestly excessive. All grounds of appeal were carefully considered and rejected. The appeal in respect of both conviction and sentence was dismissed.¹⁰¹

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.^{102, 103}

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

⁹⁹ Codex Alimentarius (2010) Codex Alimentarius Commission, General Standard for the Labelling of Prepackaged Foods. CODEX STAN 1-1985 (1985, last amended 2010).

¹⁰⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.428.01.0001.01.ENG&toc=OJ:C:2017:428:TOC

¹⁰¹ Neutral Citation Number: [2017] EWCA Crim 1783, Case No: 201603723 B3, <http://www.bailii.org/ew/cases/EWCA/Crim/2017/1783.html>

¹⁰² <https://www.fdf.org.uk/news.aspx?article=7539>

¹⁰³ <https://www.fdf.org.uk/herbs-spices-guidance.aspx>

Implementing Regulation (EU) No 828/2014,¹⁰⁴ national provisions will allow enforcement at UK level.¹⁰⁵

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 2016,¹⁹¹¹⁰⁶ 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) 2016.¹⁰⁷ 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);
- In Wales by the Food Information (Wales) (Amendment) Regulations 2016¹⁰⁸ 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.¹⁰⁹

The FSA publishes regular reports of surveys into information about the public’s self-reported behaviours, attitudes and knowledge relating to food issues. Of those who reported an adverse reaction or avoided certain foods in 2017, the most common foods that people reported having an adverse reaction to were cows’ milk and cows’ milk products (22%), cereals containing gluten (13%) and molluscs, e.g. mussels, oysters (11%).

Anaphylaxis to the trigger allergen by a sensitised individual, which is always disturbing and sometimes fatal, requires the rapid parenteral (intramuscular) administration of adrenalin. The

¹⁰⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1471529878473&uri=CELEX:32014R0828>

¹⁰⁵ <https://www.coeliac.org.uk/about-us/news/changes-to-european-legislation-on-gluten-free-labelling/>

¹⁰⁶ <http://www.legislation.gov.uk/ssi/2016/191/contents/made>

¹⁰⁷ <http://www.legislation.gov.uk/nisr/2016/249/made>

¹⁰⁸ <http://www.legislation.gov.uk/wsi/2016/664/made>

¹⁰⁹ <https://www.food.gov.uk/sites/default/files/media/document/fifth-csa-report-allergy%20%281%29.pdf>

Human Medicines (Amendment) Regulations 2017¹¹⁰ allow auto-injectors containing adrenaline to be administered in schools in an emergency to pupils who are known to require such medication. The regulations apply to England and Northern Ireland.

AOAC INTERNATIONAL (formerly Association of Official Analytical Chemists), published a special edition of its journal, J AOAC International, on food allergens. The edition contained three papers from the Government Chemist. Michael Walker, Malcolm Burns and colleagues described the science behind the ground breaking analysis for allergens by ELISA, molecular biology, and protein mass spectrometry during the investigation of the almond and mahaleb incidents in 2015. Michael and co-authors Hazel Gowland and John Points discussed managing food allergens in the UK retail supply chain in a second paper. Milena Quaglia, Kate Groves and Adam Cryar assessed recovery of food allergens from solid processed matrices applying SI (International System of Units) traceably quantified milk protein solutions and a novel extraction method in a third paper in the special edition. The special edition spanned the globe with contributions from five continents on topics as diverse as food allergen labelling and regulation, quantitative ELISA, targeted and novel mass spectrometry approaches to allergen analysis and analytical devices for use by consumers. The edition is open access and is available on the J AOAC International website.¹¹¹

In an interesting development SCIEX, the mass spectrometry company, released an application note on food allergen screening for 12 food allergens in one analysis.¹¹²

2.2 Contaminants

Regulation (EC) No 1881/2006 remains the primary European legislation, the latest consolidated version of which was published in July 2017.¹¹³ Domestic implementation is via a set of 'Contaminants in Food' regulations made in each country of the UK in 2013, for example the Contaminants in Food (England) Regulations 2013.¹¹⁴ A search of <http://www.legislation.gov.uk/> on the search term 'contaminants' will list the current statutory instruments, their amendments and predecessors. A useful summary of contaminant information is available on the European Commission website.¹¹⁵ A guidance document for competent authorities for the control of compliance with EU legislation on aflatoxins is available. Please see below for further details on individual contaminants.¹¹⁶

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

The 83rd report of the Joint FAO/WHO Expert Committee on Food Additives was published in June 2017. It includes evaluations of technical, toxicological and/or dietary exposure data for six contaminants or groups of contaminants (aflatoxins, 4,15-diacetoxyscirpenol, (DAS), fumonisins, glycidyl esters, 3-MCPD esters and 3-MCPD, sterigmatocystin) as well as an evaluation of co-exposure of fumonisins with aflatoxins.¹¹⁷

¹¹⁰ <http://www.legislation.gov.uk/ukxi/2017/715/contents/made>

¹¹¹ <http://aoac.publisher.ingentaconnect.com/content/aoac/jaoac/pre-prints.jsessionid=10vwt1ffoh7as.x-ic-live-01>

¹¹² https://sciex.com/community/blogs/blogs/screening-food-for-allergens-using-lc-ms-ms-analysis?utm_source=linkedin&utm_medium=social&utm_campaign=global+why+sciex+food&utm_term=allergens+blogs+4q17&utm_content=blog

¹¹³ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520971049904&uri=CELEX:02006R1881-20170728>

¹¹⁴ <http://www.legislation.gov.uk/ukxi/2013/2196/contents/made>

¹¹⁵ http://ec.europa.eu/food/safety/chemical_safety/contaminants/index_en.htm

¹¹⁶ https://ec.europa.eu/food/sites/food/files/safety/docs/cs_contaminants_sampling_analysis_guidance-2010_en.pdf

¹¹⁷ <http://www.who.int/foodsafety/publications/technical-report-series-1002/en/>

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) 2016/582.¹¹⁸

Polychlorinated biphenyls, PCBs, are mentioned in Council Directive 96/23/EC 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products, the annexes of which deal with official sampling. The latest consolidated version is that of 1 July 2013.¹¹⁹

2.2.2 Mycotoxins

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

In December 2016 an error was corrected in Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs. The error regarding units seems to have been introduced by Regulation (EU) No 519/2014 of 16 May 2014 in the table in Annex II that prescribed performance criteria for methods for the determination of aflatoxins. Concentrations were stated in mg kg⁻¹ and while it was no doubt generally recognised by practicing analysts that the units should be µg kg⁻¹ in keeping with the limits, a Corrigendum was issued to make this clear.¹²⁰

2.2.3 Cyanide in raw apricot kernels

An EFSA opinion¹²¹ has confirmed the acute health risks from the presence of cyanogenic glycosides in raw apricot kernels and their derived products owing to amygdalin, the major cyanogenic glycoside present, being degraded to hydrocyanic acid (cyanide) by chewing. Hydrocyanic acid (cyanide) is highly toxic and the acute reference dose would be exceeded by consumption of only a very few unprocessed apricot kernels. Thus Commission Regulation (EU) 2017/1237 of 7 July 2017¹²² amended Regulation (EC) No 1881/2006 to set a maximum level for hydrocyanic acid of 20 µg kg⁻¹ in unprocessed whole, ground, milled, cracked, or chopped apricot kernels placed on the market for the final consumer. The operator who places these products on the market for the final consumer must provide upon request from the competent authority evidence of compliance with the maximum level. Sampling for the control of compliance with the

¹¹⁸ 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

¹¹⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498122962393&uri=CELEX:01996L0023-20130701>

¹²⁰ 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

¹²¹ <https://www.efsa.europa.eu/en/efsajournal/pub/4424>

¹²² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.177.01.0036.01.ENG&toc=OJ:L:2017:177:TOC#nr3-L_2017177EN.01003601-E0003

maximum must be performed in accordance with part D.2 of Annex I to Commission Regulation (EC) No 401/2006.

2.2.4 Dioxins and related compounds

Regulation 1881/2006 establishes, with certain derogations, maximum levels for non-dioxin-like polychlorinated biphenyls (PCBs) dioxins and furans and for the sum of dioxins, furans and dioxin-like PCBs in certain foodstuffs. Please refer to previous editions of this review for further details.¹²³

Commission Recommendation 2013/711/EU¹²⁴ sets out action levels for polychlorinated dibenzo-para-dioxins and polychlorinated dibenzofurans (PCDD/Fs) and dioxin-like PCBs in food. The action levels are a tool to be used by competent authorities and food business operators to highlight those cases where it is appropriate to identify a source of contamination and to take the necessary measures in order to reduce or eliminate it.

Commission Regulation (EU) 2017/644 of 5 April 2017¹²⁵ laid down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealed Regulation (EU) No 589/2014. The rationale for additional control of sampling and analysis included ensuring that food business operators applying the controls performed within the framework of Article 4 of Regulation (EC) No 852/2004 (see Section 2.15) apply representative sampling procedures and appropriate laboratory performance criteria. Interestingly, the European Union Reference Laboratory for Dioxins and PCBs has found that analytical results in certain cases are not reliable when appropriate laboratory performance criteria are not applied by laboratories performing the analysis of samples taken by food business operators. Regulation 2017/644 also deletes the use of a decision limit as provided for in Commission Decision 2002/657/EC for the analysis of dioxins and PCBs in food, in favour of an expanded uncertainty using a coverage factor of 2, giving a level confidence of approximately 95%. The regulation also provides for reporting requirements for physico-chemical methods used for screening in line with the reporting requirements for bioanalytical screening methods and makes other minor amendments.

2.2.5 Glycidyl fatty acid esters

Glycidyl fatty acid esters (2,3-epoxy-1-propanol fatty acid esters) are process contaminants found at highest levels in refined vegetable oils and fats, e.g. refined palm oil generated where they arise during the deodorisation step. Glycidyl fatty acid esters are hydrolysed in the gastrointestinal tract to glycidol, a genotoxic carcinogen. Their formation, occurrence, analysis, and elimination have been reviewed¹²⁶ including by EFSA.¹²⁷ Commission Regulation (EU) 2018/290 of 26 February 2018¹²⁸ amended Regulation 1881/2006 to establish maximum concentrations of glycidyl fatty acid esters in vegetable oils and fats, infant formula, follow-on formula and foods for special medical purposes intended for infants and young children. The

¹²³ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/576807/Foodfeedlaw_July-Sept_16_Final.pdf

¹²⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498122697939&uri=CELEX:32013H0711>

¹²⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.092.01.0009.01.ENG&toc=OJ:L:2017:092:TOC

¹²⁶ Cheng, W.W., Liu, G.Q., Wang, L.Q. and Liu, Z.S., 2017. Glycidyl Fatty Acid Esters in Refined Edible Oils: A Review on Formation, Occurrence, Analysis, and Elimination Methods. *Comprehensive Reviews in Food Science and Food Safety*, 16(2), pp.263-281.

¹²⁷ Scientific opinion on the risks for human health related to the presence of 3- and 2-monochloropropanediol (MCPD), and their fatty acid esters, and glycidyl fatty acid esters in food. *EFSA Journal* 2016;14(5): 4426, 159 pp. doi:10.2903/j.efsa.2016.4426 <https://www.efsa.europa.eu/en/efsajournal/pub/4426>

¹²⁸ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.055.01.0027.01.ENG&toc=OJ:L:2018:055:TOC

maxima are: 1000 µg kg⁻¹ for vegetable oils and fats placed on the market for the final consumer or for use as an ingredient in food with the exception of:

1. vegetable oils and fats destined for the production of baby food and processed cereal-based food for infants and young children 500 µg kg⁻¹;
2. infant formula, follow-on formula and foods for special medical purposes intended for infants and young children (powder) 75 µg kg⁻¹ until 30 June 2019 and 50 µg kg⁻¹ as from 1 July 2019;
3. infant formula, follow-on formula and foods for special medical purposes intended for infants and young children (liquid) 10.0 µg kg⁻¹ until 30 June 2019 and 6.0 µg kg⁻¹ as from 1 July 2019.

2.2.6 Seaweed – metals and iodine

Commission Recommendation (EU) 2018/464 of 19 March 2018¹²⁹ advised Member States and food and feed business operators to monitor the concentrations of arsenic, cadmium, iodine, lead and mercury in seaweed, halophytes (plants growing in waters of high salinity) and products based on seaweed. Examples include bladderwrack, dulse, Irish moss, purple laver and types of kelp. There are currently no maximum limits in Regulation 1881/2006 for these substances in seaweed and halophytes, except for seaweed based food supplements. For mercury, currently under Regulation (EC) No 396/2005 a maximum residue level (MRL) for algae and prokaryotic organisms is established at the default level of 0.01 mg kg⁻¹. Seaweed and halophytes form an increasingly important contribution to the consumption patterns of certain EU consumers hence data are required to enable an accurate estimation of exposure. Occurrence data should also be gathered for food additives based on seaweed, including E400, E401, E403, E404, E405, E406, E407, E407a and E160a(iv). Basic sampling and analysis advice is given, e.g. methylmercury and total mercury should preferably be measured and the analysis of arsenic should include inorganic and total arsenic and, if possible, other relevant arsenic species.

In 2006 the Scientific Committee for food established an upper limit for iodine intake of 600 µg per day for adults and of 200 µg a day for children of 1-3 years. It indicated that the ingestion of iodine-rich algal products, particularly dried products, can lead to dangerously excessive iodine intakes, if such products contain more than 20 mg iodine/kg dry matter and the exposed population lives in an area of endemic iodine deficiency.

In relation to iodine see also Section 3.6, Novel Foods: Regulation (EU) 2018/460 of 20 March 2018 authorised the placing on the market of *Ecklonia cava* phlorotannins as a novel food.

2.3 Non regulated contaminants

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

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

¹²⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.078.01.0016.01.ENG&toc=OJ:L:2018:078:TOC

Updates on the above are in previous editions of this review¹³⁰ 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)¹³¹ to help people understand how to minimise exposure to acrylamide when cooking at home.

In November 2017 Commission Regulation (EU) 2017/2158¹³² established mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food. Based on EFSA conclusions with respect to the carcinogenic effects of acrylamide and in the absence of any consistent and mandatory measures to be applied by food businesses in order to lower levels of acrylamide, it was considered necessary to reduce the presence of acrylamide in foodstuffs where raw materials contain its precursors by laying down appropriate mitigation measures. The approaches include implementation of good hygiene practice and application of hazard analysis and critical control point (HACCP) principles. Procedures are set out in the Regulation to allow the reduction of the level of exposure to acrylamide and benchmark concentrations have been developed to gauge the effectiveness of mitigation through sampling and analysis which is required of food businesses. Official controls should include sampling and analysis. The benchmark concentrations will be regularly reviewed by the Commission and complementary to this Regulation, the setting of maximum concentrations for acrylamide in certain foods will be considered in accordance with Regulation (EEC) No 315/93 following the entry into force of this Regulation which will apply from 11 April 2018.

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

The benchmark acrylamide concentrations range from 40 $\mu\text{g kg}^{-1}$ for certain baby foods, 500 $\mu\text{g kg}^{-1}$ for ready-to-eat chips (French fries), 750 $\mu\text{g kg}^{-1}$ for potato crisps, to 850 $\mu\text{g kg}^{-1}$ for instant (soluble) coffee. Readers should consult the Regulation for details of the mitigation

¹³⁰ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/576807/Foodfeedlaw_July-Sept_16_Final.pdf

¹³¹ <https://www.food.gov.uk/news-updates/news/2017/15890/reduce-acrylamide-consumption>

¹³² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.304.01.0024.01.ENG&toc=OJ:L:2017:304:TOC

measures, however in brief these include, for example for chips, the use of potato varieties with lower sugar content and storage of potatoes at a temperature higher than 6 °C, washing the potato chips prior to frying, and frying temperatures below 175 °C.

See also the FSA website section on acrylamide¹³³ and FoodDrink Europe toolkits.¹³⁴ FSA and FSS are working with the British Hospitality Association and other key stakeholders to develop simple guidance which will help the catering and foodservice sectors comply with new rules. Guidelines to aid understanding of the enforcement of the legislation will also be available in 2018.¹³⁵

2.4 Food additives

Annex II to Regulation (EC) No 1333/2008 lays down a European Union list of food additives approved for use in foods and their conditions of use, and Annex I to Regulation (EC) No 1334/2008 lays down a European Union list of flavourings and source materials approved for use in and on foods and their conditions of use. Commission non-official guidance describes the food categories in Part E of Annex II to Regulation 1333/2008.¹³⁶

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.¹³⁷⁻¹⁴⁰

A database of additives is available on the European Commission website,¹⁴¹ 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.¹⁴²

Regulation (EU) No 231/2012¹⁴³ sets specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008. A compendium of food additive specifications is available online.¹⁴⁴

The WHO Food Additives Series: 73 prepared by the 82nd meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was published in November 2017 and included safety evaluations of allura red, carob bean gum, pectin, quinoline yellow, rosemary extract, steviol glycosides, tartrazine xanthan gum and certain flavourings.¹⁴⁵

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) 2015/2203¹⁴⁶ on caseins and caseinates intended for human consumption. A food

¹³³ <https://www.food.gov.uk/safety-hygiene/acrylamide>

¹³⁴ <https://www.fooddrinkeurope.eu/publications/category/toolkits/>

¹³⁵ <https://www.food.gov.uk/business-guidance/acrylamide-legislation>

¹³⁶ http://ec.europa.eu/food/food/FAEF/additives/guidance_en_print.htm

¹³⁷ <http://www.legislation.gov.uk/ukxi/2013/2210/contents/made>

¹³⁸ <http://www.legislation.gov.uk/wsi/2013/2591/contents/made>

¹³⁹ <http://www.legislation.gov.uk/ssi/2013/266/contents/made>

¹⁴⁰ <http://www.legislation.gov.uk/nisr/2013/220/contents/made>

¹⁴¹ http://ec.europa.eu/food/safety/food_improvement_agents/additives/database_en

¹⁴² <https://www.food.gov.uk/sites/default/files/media/document/food-additives-legislation-guidance-to-compliance.pdf>

¹⁴³ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1499108628009&uri=CELEX:02012R0231-20170317>

¹⁴⁴ <http://www.fao.org/3/a-i6413e.pdf>

¹⁴⁵ <http://apps.who.int/iris/bitstream/10665/258934/1/9789241660730-eng.pdf>

¹⁴⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1466676596182&uri=CELEX:32015L2203>

category “edible caseinates” was established and the additives authorised in edible caseinates included with the respective conditions of use by Commission Regulation (EU) 2016/691 of 4 May 2016.¹⁴⁷ Compositional standards for caseinates are given in the Directive, see Section 3.3.1.

2.4.2 Gel forming additives in jelly confectionery

Certain gel forming additives are prohibited in jelly confectionery that conforms with the definition of ‘jelly mini-cups’ given in Part E of Annex II of Regulation 1333/2008. A summary of the background to this, testing products to assess if they conform to the definition of a ‘jelly mini-cup’ and technical appeals to the Government Chemist in this area was published in the September 2017 edition of the IFST house journal FS&T.¹⁴⁸

2.4.3 Nitrites – Denmark national provisions

Commission Decision (EU) 2018/702 of 8 May 2018 (notified under document C(2018) 2721) approved national provisions in Denmark which are more stringent than those of Regulation (EC) No 1333/2008 for the addition of nitrite to certain meat products. A lower maximum of 60 mg kg⁻¹ applies against corresponding maxima in Regulation 1333/2008 of 100 mg kg⁻¹ or 150 mg kg⁻¹. The Danish authorities supplied data on consumption of meat products, exposure to nitrites, the prevalence of botulism and the formation of nitrosamines. The decision document should be considered for a fully reasoned opinion. However, in brief, the Commission, advised by EFSA, took into account the health benefits invoked by the Danish government on reduction of exposure to nitrites in meat products and that trade does not appear to be affected at all or only to a very limited extent. The national provisions are approved subject to monitoring conditions for a limited period of 3 years.¹⁴⁹

2.4.4 Polyglycerol polyricinoleate

Annex II to Regulation 1333/2008 authorised polyglycerol polyricinoleate (E 476) in ‘Sauces’ (to a maximum of 4 000 mg kg⁻¹), but only for dressings. Commission Regulation (EU) 2018/682 of 4 May 2018 amended Annex II to Regulation 1333/2008 to extend the use of polyglycerol polyricinoleate to emulsified sauces to the same maximum.¹⁵⁰

In accordance with Annex II to Regulation 1333/2008, polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209) is authorised as a food additive in the food category 17.1 ‘food supplements supplied in a solid form including capsules and tablets, excluding chewable forms’. According to the current EU specifications, the maximum permissible amount of ethylene glycol and diethylene glycol, which are present as impurities in the food additive polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209), is 50 mg kg⁻¹ for each of them. Following an application to increase this to 620 mg kg⁻¹, and consultations including with EFSA, the concentration was increased to ‘not more than 400 mg kg⁻¹ for ethylene glycol individually or in combination with diethylene glycol’ in line with JECFA specifications.¹⁵¹

¹⁴⁷ 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

¹⁴⁸ <https://www.fstjournal.org/features/31-3/choking-hazards>

¹⁴⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1529848018164&uri=CELEX:32018D0702>

¹⁵⁰ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.116.01.0005.01.ENG&toc=OJ:L:2018:116:TOC

¹⁵¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.116.01.0001.01.ENG&toc=OJ:L:2018:116:TOC

2.4.5 Potassium carbonate

Commission Regulation (EU) 2017/1270 of 14 July 2017¹⁵² amended Annex II to Regulation 1333/2008 to allow the use of potassium carbonate (E501) on peeled, cut and shredded fruit and vegetables at *quantum satis* levels. The salt is permitted only in prepacked refrigerated unprocessed fruit and vegetables ready for consumption and prepacked unprocessed and peeled potatoes. During preparation of fresh cut fruit and vegetables, enzymatic activities may lead to a loss in quality of the products, such as browning and structural losses, and to food waste. In order to avoid browning, ascorbic acid (E300) can be used. However, ascorbic acid tends to break down cell tissue, leading to softening and discoloration of fruit and vegetables after a few days. The use of potassium carbonate (E501) allows for a more efficient protection against browning as it functions as a stabilizer and acidity regulator and minimizes the damage to tissue caused by ascorbic acid.

2.4.6 Propellants in colour preparations

Commission Regulation (EU) 2017/874 of 22 May 2017 amended Annex III to Regulation 1333/2008 to permit the use of butane (E943a), isobutane (E943b) and propane (E944) in sprays in order to obtain an appropriate homogenous coverage of colours on foods.¹⁵³

2.4.7 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 SO₂ equivalent/kg bw per day (derived using a default uncertainty factor of 100) would remain adequate but should be considered temporary whilst the database was improved. The EFSA Panel further concluded that exposure estimates to sulphur dioxide-sulphites were higher than the group ADI for all population groups.¹⁵⁴

2.4.8 Thaumatin

Commission Regulation (EU) 2018/677 of 3 May 2018 amended Annex II to Regulation 1333/2008 to extend the use of Thaumatin (E 957) as a flavour enhancer in 'Sauces' and 'Potato, cereal-, flour- or starch-based snacks' at a maximum level of 5 mg kg⁻¹ in each food category.¹⁵⁵

2.4.9 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.¹⁵⁶

¹⁵² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.184.01.0001.01.ENG&toc=OJ:L:2017:184:TOC

¹⁵³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.134.01.0018.01.ENG&toc=OJ:L:2017:134:TOC

¹⁵⁴ http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4438.pdf

¹⁵⁵ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.114.01.0010.01.ENG&toc=OJ:L:2018:114:TOC

¹⁵⁶ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/576807/Foodfeedlaw_July-Sept_16_Final.pdf

Commission Regulation (EU) 2017/1399 of 28 July 2017¹⁵⁷ amended Annex II to Regulation 1333/2008 to permit potassium polyaspartate, E456. Potassium polyaspartate acts as a stabiliser against tartrate crystal precipitation in wine (red, rosé and white wine). It enhances the keeping quality and stability of wine and its use does not have an impact on the sensory properties. The proposed use in wine is at a maximum of 300 mg L⁻¹ with typical levels in the range of 100-200 mg L⁻¹.

Commission Delegated Regulation (EU) 2017/1961 of 2 August 2017 amended Regulation (EC) No 606/2009 to permit the use of filter plates containing zeolites γ -faujasite to adsorb haloanisoles and the treatment of wine with potassium polyaspartate.¹⁵⁸

2.4.10 Additives in additives

Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use. Commission Regulation (EU) 2017/1271 of 14 July 2017¹⁵⁹ amended Annex III to permit the use of silicon dioxide (E551) as an anticaking agent in potassium nitrate (E252) up to 10,000 mg kg⁻¹.

2.4.11 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 2008.¹⁶⁰ The regulation is regularly updated, readers should refer to Eur Lex for the latest version as significant amendments are mentioned here on a quarterly basis but only major updates are retained.

In July 2017 Commission Regulation (EU) 2017/1250 amended Annex I to Regulation 1334/2008 to remove from the EU permitted list the flavouring substance 4,5-epoxydec-2(trans)-enal following an EFSA opinion which raised a safety concern with respect to genotoxicity.¹⁶¹

Commission Regulation (EU) 2018/678 of 3 May 2018 corrected some minor errors in Annex I to Regulation 1334/2008.¹⁶²

Commission Regulation (EU) 2018/1246¹⁶³ of 18 September 2018 amended Annex I to Regulation (EC) No 1334/2008 to allow inclusion of pyroligneous distillate (FL no. 21.001, 'rum ether') in the EU list of flavourings. EFSA¹⁶⁴ noted this product is a complex mixture of more than eighty individual constituents and that the presence of genotoxic substances is of safety concern, e.g. furans and other constituents associated with genotoxicity and carcinogenicity. However the Czech and the Slovak Republics asked the Commission to retain use of pyroligneous distillate in the traditional spirit drinks *tuzemák* and *tuzemský*. Accordingly, Regulation 2018/1246 permits the flavouring in these specific spirit drinks with a reference in their labelling to its presence. Contrary to the request of the applicant company it is not permitted in any other food or drink.

¹⁵⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.199.01.0008.01.ENG&toc=OJ:L:2017:199:TOC

¹⁵⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.279.01.0025.01.ENG&toc=OJ:L:2017:279:TOC

¹⁵⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.184.01.0003.01.ENG&toc=OJ:L:2017:184:TOC

¹⁶⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1445980490072&uri=CELEX:02008R1334-20150729>

¹⁶¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.179.01.0003.01.ENG&toc=OJ:L:2017:179:TOC

¹⁶² https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.114.01.0013.01.ENG&toc=OJ:L:2018:114:TOC

¹⁶³ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.235.01.0003.01.ENG&toc=OJ:L:2018:235:TOC#ntr5-L_2018235EN.01000301-E0005

¹⁶⁴ EFSA Journal 2017;15(8):4897.

Commission Regulation (EU) 2018/1259 of 20 September 2018¹⁶⁵ amended Regulation (EU) No 873/2012 on transitional measures concerning the EU list of flavourings and source materials set out in Annex I to Regulation (EC) No 1334/2008. This was to allow products already on the market or labelled prior to 22 April 2010 and containing the flavouring 'grill flavour concentrate (vegetable)' FL No 21.002 to be sold until the end of their date of minimum durability or use-by-date. The application for the approval of the flavouring had been received two days before the expiry date for applications (22 October 2015) and a transition period is appropriate while studies requested by EFSA are completed.

2.4.12 Phosphates

Commission Regulation (EU) 2018/74 of 17 January 2018 amended Annex II to Regulation 1333/2008 to extend the use of phosphoric acid, phosphates and di-, tri- and polyphosphates (E338-452) to use in frozen vertical meat spits (e.g. for doner kebabs). This followed a 2015 application for the authorisation of these additives as stabilisers and humectants in frozen vertical meat spits falling under the food category 08.2 'Meat preparations as defined by Regulation (EC) No 853/2004' in Part E of Annex II to Regulation (EC) No 1333/2008. The recital to Regulation 2018/74 explains that use of phosphates is required for a partial extraction and breakdown of meat proteins to form a protein film on vertical meat spits to bond meat pieces together in order to ensure homogenous freezing and roasting. The recital goes on to state that " ... phosphates ensure that meat remains juicy during thawing and that vertical meat spits remain stable." This technological need was recognised for frozen vertical rotating meat spits made of sheep, lamb, veal or beef treated with liquid seasoning or from poultry meat treated with or without liquid seasoning used alone or combined as well as sliced or minced and designed to be roasted by a food business operator. Thoroughly roasted meat strips are then consumed by the final consumer. The application was regarded not to pose a food safety risk. The maximum limit is 5000 mg kg⁻¹ as P₂O₅.¹⁶⁶

2.4.13 Microcrystalline cellulose

Commission Regulation (EU) 2018/75 of 17 January 2018 amended the Annex to Regulation 231/2012 on specifications for food additives to correct the solubility criteria in the specification for microcrystalline cellulose (E460(i)). This now states: "insoluble in water, ethanol, ether and dilute mineral acids. Practically insoluble or insoluble in sodium hydroxide solution (concentration: 50 g NaOH/L)."¹⁶⁷

2.4.14 Sweeteners no longer permitted in fine bakery wares

Commission Regulation (EU) 2018/97 of 22 January 2018 amended Annex II to Regulation 1333/2008 to delete the use of sweeteners in fine bakery wares. Directive 94/35/EC authorised the use of sweeteners in 'fine bakery products for special nutritional uses' which also covered 'foods for persons suffering from carbohydrate metabolism disorders (diabetes)' regulated by Council Directive 89/398/EEC. However, the scientific basis for setting specific compositional requirements for those foods was lacking and Regulation 609/2013 abolished the concept of 'foodstuffs for particular nutritional uses', including that of 'food for persons suffering from carbohydrate metabolism disorders (diabetes)'. Therefore, the authorisation of E950 Acesulfame K, E951 Aspartame, E952 Cyclamic acid and its Na and Ca salts, E954 Saccharin and its Na, K

¹⁶⁵ <https://eur-lex.europa.eu/eli/reg/2018/1259/oj>

¹⁶⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.013.01.0021.01.ENG&toc=OJ:L:2018:013:TOC

¹⁶⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.013.01.0024.01.ENG&toc=OJ:L:2018:013:TOC

and Ca salts, E955 Sucralose, E959 Neohesperidine DC, E961 Neotame, E962 Salt of aspartame-acesulfame and E969 Advantame in 'fine bakery products for special nutritional uses' in accordance with Article 7(c) of Regulation (EC) No 1333/2008 is no longer justified.¹⁶⁸

2.4.15 Calcium sorbate prohibited

Commission Regulation (EU) 2018/98 of 22 January 2018 amended Annexes II and III to Regulation 1333/2008 and the Annex to Commission Regulation 231/2012 to delete references to the preservative calcium sorbate (E203). Following a call from EFSA for genotoxicity data on calcium sorbate, pursuant to its programme for the re-evaluation of food additives laid down in the Commission Regulation (EU) No 257/2010, no data were forthcoming. Thus calcium sorbate has been removed from the EU list of approved food additives. Sorbic acid and potassium sorbate remain on the list.¹⁶⁹

2.5 Endocrine disrupting compounds

There is growing interest in the possible health threat posed by endocrine-disrupting chemicals in the environment, food, and consumer products. Endocrine-disrupting compounds interfere with hormone biosynthesis, metabolism, or action resulting in a deviation from normal homeostatic control or reproduction and may have effects on male and female reproduction, breast development and cancer, prostate cancer, neuroendocrinology, thyroid, metabolism and obesity, and cardiovascular endocrinology. The group of molecules identified as potential endocrine disruptors is highly heterogeneous, structurally diverse and includes polychlorinated biphenyls (PCBs), polybrominated biphenyls (PBBs), dioxins, bisphenol A (BPA), phthalates, some pesticides, and pharmaceutical agents such as diethylstilbestrol (DES). Natural chemicals found in human and animal food (e.g., phytoestrogens, including genistein and coumestrol) can also act as endocrine disruptors although with lower binding affinity to receptors than the above compounds.¹⁷⁰

Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017¹⁷¹ set out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council. The full definition is set out in an Annex. A substance shall be considered as having endocrine-disrupting properties with respect to humans or non-target organisms, where it meets the criteria set out in section A or section B of the Annex. With regard to humans a substance shall be considered as having endocrine-disrupting properties if it shows a defined adverse effect in an intact organism or its progeny, has an endocrine mode of action and the adverse effect is a consequence this as assessed by defined scientific evaluation. With respect to non-target organisms the criteria are similar.

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

¹⁶⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.017.01.0011.01.ENG&toc=OJ:L:2018:017:TOC

¹⁶⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.017.01.0014.01.ENG&toc=OJ:L:2018:017:TOC

¹⁷⁰ Diamanti-Kandarakis E., Bourguignon J. P., Giudice L. C., Hauser R., Prins G. S., Soto A. M., Zoeller R. T. and Gore A. C. (2009) Endocrine-disrupting chemicals: an Endocrine Society scientific statement, *Endocrine reviews*, 30(4): 293-342

¹⁷¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.301.01.0001.01.ENG&toc=OJ:L:2017:301:TOC

endocrine systems, the effects on organisms of the same taxonomic phylum as the targeted one shall not be considered for the identification of the substance as having endocrine-disrupting properties with respect to non-target organisms.

Commission Regulation (EU) 2018/605 of 19 April 2018¹⁷² amended Annex II to Regulation (EC) No 1107/2009 concerning the placing of plant protection products (pesticides) on the market by setting out scientific criteria for the determination of endocrine disrupting properties in similar terms to Regulation 2017/2100. A weight of evidence approach is advocated for example the approach provided for in Regulation (EC) No 1272/2008¹⁷³ on classification, labelling and packaging of substances and mixtures. See also Balls *et al.*, 2006.¹⁷⁴ A Corrigendum was issued to Regulation 2018/605 correcting relevant dates from October to November in 2018 and 2025 as the regulation applied in each of those years.¹⁷⁵

2.6 Extraction solvents

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

2.7 Food contact materials (FCM)

Regulation (EC) No 1935/2004¹⁷⁶ 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.¹⁷⁷

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.^{178, 179}

¹⁷² https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.101.01.0033.01.ENG&toc=OJ:L:2018:101:TOC

¹⁷³ <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1529752734953&uri=CELEX:02008R1272-20180301>

¹⁷⁴ Balls, M., Amcoff, P., Bremer, S., Casati, S., Coecke, S., Clothier, R., ... Zuang, V. (2006). The Principles of Weight of Evidence Validation of Test Methods and Testing Strategies: The Report and Recommendations of ECVAM Workshop 58. *Alternatives to Laboratory Animals : ATLA*, 34(6), 603–620 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2709979/>

¹⁷⁵ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.111.01.0010.01.ENG&toc=OJ:L:2018:111:TOC

¹⁷⁶ See EUR-Lex for up to date versions of legislation: <http://eur-lex.europa.eu/homepage.html>

¹⁷⁷ 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>

¹⁷⁸ http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation/index_en.htm

¹⁷⁹ http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/index_en.htm

Regulation 10/2009 has been extensively amended by Commission Regulation (EU) 2016/1416¹⁸⁰ and Commission Regulation (EU) 2017/752 of 28 April 2017¹⁸¹. Relevant EFSA opinions were incorporated and textual errors corrected, the definition 'hot-fill' was clarified, and other technical clarifications made including new specific migration limits. In addition in Annex III Table 3, "Food simulants for tests to demonstrate compliance with the overall migration limit", was updated. In Annex IV, point 8(iii) was replaced by '(iii) the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information'.

Commission Regulation (EU) 2018/831 of 5 June 2018 amended Regulation 10/2011, Annex I, in respect of certain entries concerning FCM substances. For entry No 822 the specific migration limit (SML) for 'perchloric acid, salts' was reduced from 0.05 mg kg⁻¹ to 0.002 mg kg⁻¹. For No 974 (phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters) the SML was increased from 5 mg kg⁻¹ to 10 mg kg⁻¹. Entries were added for 1066 1,2,3,4-tetrahydronaphthalene-2,6-dicarboxylic acid, dimethyl ester and 1068 [3-(2,3-epoxypropoxy)propyl]trimethoxy silane.¹⁸²

2.7.1 Recycled plastic

Commission Regulation 2015/1906¹⁸³ 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.

2.7.2 Domestic implementation

In August 2017 the Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2017¹⁸⁴ amended the Materials and Articles in Contact with Food Regulations (Northern Ireland) 2012 to provide for the continued enforcement of Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food) as amended by Commission Regulation (EU) No. 2016/1416. Those amendments include removal of certain offences so as to enable improvement notices to be served to require the same compliance. The failure to comply with an improvement notice becomes an offence under Article 9(2) of the Food Safety (Northern Ireland) Order 1991 (regulation 12 and 14). Examples include, in the 2012 regulations, regulations 7(2) (obligation under Art. 13 of Regulation 450/2009 on supporting documentation), 14(2) (making available certain compositional details to competent authorities), 16(4) (prohibition of use of BFDGE,¹⁸⁵ NOGE¹⁸⁶ and contravention of the specific migration limit for BADGE¹⁸⁷ and certain derivatives) and others. Consequential administrative amendments are also made.

In Wales the equivalent Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017, Rheoliadau Deunyddiau ac Eitemau mewn Cysylltiad â Bwyd (Cymru) (Diwygio) 2017 were made.¹⁸⁸

¹⁸⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1416>

¹⁸¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.113.01.0018.01.ENG&toc=OJ:L:2017:113:TOC

¹⁸² https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.140.01.0035.01.ENG&toc=OJ:L:2018:140:TOC

¹⁸³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.278.01.0011.01.ENG

¹⁸⁴ <http://www.legislation.gov.uk/nisr/2017/157/contents/made>

¹⁸⁵ BFDGE, bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers, or Bisphenol-F DiGlycidyl Ether

¹⁸⁶ NOGE, novolac glycidyl ethers.

¹⁸⁷ BADGE, 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether or Bisphenol-A DiGlycidyl Ether

¹⁸⁸ <http://www.legislation.gov.uk/wsi/2017/832/contents/made>

2.7.3 Updates on permitted substances and monomers

Following favourable EFSA opinions Commission Regulation (EU) 2018/79 of 18 January 2018 updated Regulation (EU) No 10/2011 on plastic materials and articles with the following substances that may be used in food contact materials:

- a) butadiene, styrene, methyl methacrylate, butyl acrylate copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate (FCM substance No 856 and CAS No 25101-28-4;
- b) the monomer 2,4,4'-trifluorobenzophenone (FCM substance No 1061 and CAS No 80512-44-3;
- c) the monomer 2,3,3,4,4,5,5-heptafluoro-1-pentene (FCM substance No 1063 and CAS No 1547-26-8;
- d) tungsten oxide (WOn (n = 2,72-2,90)) (FCM substance No 1064 and CAS No 39318-18-8;
- e) the mixture of methyl-branched and linear C14-C18 alkanamides, derived from fatty acids (FCM substance No 1065 and CAS No 85711-28-0.

Please refer to the Regulation for conditions of use for the above.¹⁸⁹

2.7.4 Bisphenol A

The substance 2,2-bis(4-hydroxyphenyl)propane (CAS 000080-05-7), commonly known as bisphenol A (BPA) is used in the manufacture of certain materials and articles intended to come into contact with food, such as polycarbonates and epoxy resins used in varnishes and coatings. BPA can migrate into food from the material or article with which it is in contact, resulting in exposure to BPA for consumers of those foods.

Commission Regulation (EU) 2018/213 of 12 February 2018¹⁹⁰ amended Regulation 10/2011 to establish a new specific migration limit (SML) of 0.05 mg of BPA per kg of food, applicable to varnishes and coatings intended to come into contact with food, and plastic food contact materials. The Regulation also sets out rules for verification of compliance, including for migration testing and expression of results and requirements for a written declaration of compliance from the responsible business operator.

The recitals to the Regulation explain that the use of BPA as a monomer in the production of plastic materials and articles is authorised by Regulation 10/2011 with a previous SML of 0.6 mg of BPA per kg of food. EFSA reviewed BPA in 2006,¹⁹¹ 2008,¹⁹² 2010¹⁹³ and 2011.¹⁹⁴ A prohibition is in place on its use in the manufacture of polycarbonate infant feeding bottles on the basis of the precautionary principle. EFSA carried out a further evaluation, published in 2015¹⁹⁵ which resulted in a new temporary Tolerable Daily Intake (t-TDI) of 4 µg/kg bw per day incorporating an overall uncertainty factor of 150. The 2015 BPA risk assessment accounted for uncertainties related to possible BPA effects at low doses on mammary gland, reproductive, neurological, immune and/or metabolic systems. The TDI is temporary pending the anticipated

¹⁸⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.014.01.0031.01.ENG&toc=OJ:L:2018:014:TOC

¹⁹⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.041.01.0006.01.ENG&toc=OJ:L:2018:041:TOC

¹⁹¹ The EFSA Journal (2006) 428, 1.

¹⁹² The EFSA Journal (2008) 759, 1.

¹⁹³ The EFSA Journal 2010;8(9):1829.

¹⁹⁴ The EFSA Journal 2011;9(12):2475

¹⁹⁵ EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2015. Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs, <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.3978/epdf>

outcome of a long-term toxicity study on BPA in rodents being undertaken by the National Toxicology Program/Food and Drug Administration (NTP/FDA) in the US. EFSA noted that central estimates for aggregated exposure to BPA through dietary and non-dietary sources¹⁹⁶ for the highest exposed groups including infants, children and adolescents, are below the t-TDI and that the health concern for BPA is low at the estimated levels of aggregated exposure.

The setting of the revised SML is based on the t-TDI, uses a conventional exposure assumption that 1 kg of food is consumed daily by a person of 60 kg body weight and takes into account non-dietary sources of BPA including non-canned meat and meat products which were found to be a major contributor to BPA exposure for some population groups. Pursuant to Article 5(1)(e) of Regulation 1935/2004 an allocation factor of 20% if the t-TDI was considered appropriate when setting the SML.

EFSA in 2016¹⁹⁷ considered new evidence which added to the indications of developmental immunotoxicity of BPA. Further precautionary steps were taken in particular as regards infants and young children, where developmental effects could be irreversible and would last a life-time. Thus BPA should not be used to manufacture polycarbonate drinking cups or bottles which are intended for infants and young children as defined in Regulation (EU) No 609/2013.

BPA is used extensively in epoxy resins for varnishes and coatings, particularly for application on the interior of food cans. While specific measures provided for in Article 5 of Regulation 1935/2004 have been adopted as regards BPA in plastic materials and articles, such measures had not been adopted as regards BPA in varnishes and coatings at EU level and Member States were able to maintain or adopt national provisions which became divergent. Thus Regulation 2018/213 of 12 February 2018 applies the same SML to varnishes and coatings applied to materials and articles, where that varnish or coating has been produced using BPA.

However, BPA must not migrate from varnishes and coatings applied to materials or articles specifically intended to come into contact with food intended for infants and young children as referred to in Regulation (EU) No 609/2013, namely infant formula, follow-on formula, processed cereal-based food, baby food, food for special medical purposes developed to satisfy the nutritional requirements of infants and young children or milk-based drinks and similar products specifically intended for young children.

Varnished or coated materials and articles and plastic materials and articles that were lawfully placed on the market before 6 September 2018 may remain on the market until exhaustion of stocks.

On 9 March 2018 EFSA launched a public call for data in order to acquire documented information (published, unpublished or newly generated) to be used for the hazard assessment of BPA. The deadline for submission was 1 August 2018.

¹⁹⁶ Non-dietary sources include exposure through air, ingestion of dust and uptake through the skin as a result of contact with thermal paper and cosmetics.

¹⁹⁷ EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), Silano *et al.*, A statement on the developmental immunotoxicity of bisphenol A (BPA): answer to the question from the Dutch Ministry of Health, Welfare and Sport. EFSA Journal 2016;14(10):4580, 22 pp. doi:10.2903/j.efsa.2016.4580
<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4580/epdf>

2.7.5 Mineral oil hydrocarbons (MOH)

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

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

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

Commission Recommendation (EU) 2017/84 of 16 January 2017¹⁹⁸ 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.

2.8 Marine biotoxins

The overarching law is Regulation (EC) No 853/2004¹⁹⁹ 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

¹⁹⁸ 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

¹⁹⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1494593945343&uri=CELEX:02004R0853-20160401>

(e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

Regulation 853/2004 is given effect in Scotland by the Food Hygiene (Scotland) Regulations 2006²⁰⁰ last amended in 2016. In England the Food Safety and Hygiene (England) Regulations 2013 apply.²⁰¹ Recognised testing methods for marine biotoxins are described in Annex III of Commission Regulation (EC) No 2074/2005 of 5 December 2005.²⁰² Further information is available from FSA²⁰³ on fish and shellfish and from FSS.²⁰⁴ EFSA have published a number of opinions on marine biotoxins and further information is also available from the Centre for Environment, Fisheries and Aquaculture Science (Cefas)²⁰⁵ and the Agri-Food & Biosciences Institute (AFBI).²⁰⁶

Commission Regulation (EU) 2017/1980 of 31 October 2017²⁰⁷ amended Annex III to Regulation (EC) No 2074/2005 on the detection method for paralytic shellfish poison (PSP). The PSP content of edible parts of molluscs (the whole body or any part edible separately) must be detected in accordance with the biological testing method or any other internationally recognised method. However if the results are challenged, the reference method shall be the so-called Lawrence method as published in AOAC Official Method 2005.06 (pre-column oxidation liquid chromatography with fluorescence detection, see for example²⁰⁸).

Commission Implementing Regulation (EU) 2017/2369 of 18 December 2017 extended to 31 December 2021 the provisions of Implementing Regulation (EU) No 743/2013 introducing protective measures on imports of bivalve molluscs from Turkey intended for human consumption. The measures include a ban on importation of live and chilled bivalve molluscs, and testing for *Escherichia coli* and marine biotoxins in all consignments of frozen bivalve molluscs. The extension arose from deficiencies in the official control system, notably in the performance of laboratories.²⁰⁹

2.9 Pesticides

Guidance on maximum residue levels (MRLs) for pesticides and analytical methods is given on the Commission website.²¹⁰ Commission Implementing Regulation (EU) 2017/660 of 6 April 2017 extended previous coordinated multiannual control programme to ensure compliance with MRLs and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin to 2018, 2019 and 2020 with amended provisions.²¹¹

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.^{212, 213}

²⁰⁰ <http://www.legislation.gov.uk/ssi/2006/3/regulation/13/made>

²⁰¹ <http://www.legislation.gov.uk/ukxi/2013/2996/contents/made>

²⁰² <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1494594527755&uri=CELEX:02005R2074-20160603>

²⁰³ <https://www.food.gov.uk/business-guidance/industry-specific-advice/fish-and-shellfish>

²⁰⁴ <http://www.foodstandards.gov.scot/food-safety-standards/advice-business-and-industry/shellfish>

²⁰⁵ <https://www.cefas.co.uk/>

²⁰⁶ <https://www.afbini.gov.uk/articles/marine-biotoxins-shellfish>

²⁰⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.285.01.0008.01.ENG&toc=OJ:L:2017:285:TOC

²⁰⁸ https://www.food.gov.uk/sites/default/files/media/document/fs235002a-zb1807-scallops_0.pdf

²⁰⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.337.01.0026.01.ENG&toc=OJ:L:2017:337:TOC

²¹⁰ http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

²¹¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.094.01.0012.01.ENG&toc=OJ:L:2017:094:TOC

²¹² <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>

²¹³ http://ec.europa.eu/food/plant/pesticides/max_residue_levels/index_en.htm

Commission Regulation (EU) 2018/62 of 17 January 2018 replaced the entire Annex I to Regulation (EC) No 396/2005. This was in order to include plant and animal product synonyms, scientific species names and the part of the product to which the respective MRLs apply. Footnote texts were updated for clarity, new footnotes added, including clarification that MRLs for pesticides in honey are not applicable to other apiculture products and obsolete footnotes deleted.²¹⁴

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.²¹⁵ Regulation 1107/2009 is implemented by Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011²¹⁶ which is frequently updated.

Commission Regulation (EU) No 546/2011 of 10 June 2011 implemented Regulation 1107/2009 as regards uniform principles for evaluation and authorisation of plant protection products, including references to analytical methods. This regulation was amended by Commission Regulation (EU) 2018/676 of 3 May 2018 to correct a reference to the quality of water intended for human consumption where Council Directive 98/83/EC should have been cited rather than Directive 2006/118/EC which concerns the protection of groundwater against pollution and deterioration.²¹⁷

Commission Regulation (EU) 2017/1432 of 7 August 2017²¹⁸ amended Regulation 1107/2009 on criteria for the approval of low-risk active substances which the latter aims at facilitating placing on the market by setting criteria for their identification and accelerating the approval procedure. However there are in the Regulation 14 classes of substances, such as carcinogens or skin sensitisers, which cannot be considered low risk. Regulation 2017/1432 adds as low-risk substances semio-chemicals, which are substances emitted by plants, animals and other organisms which are used for intra- and inter-species communication, have a target-specific and non-toxic mode of action and are naturally occurring. They are generally effective at very low rates, often comparable to levels that occur naturally. Certain micro-organisms may also be considered to be of low-risk unless at strain level multiple resistance to antimicrobials used in human or veterinary medicine has been demonstrated. Certain baculoviruses may also be considered low risk unless, at strain level, adverse effects on non-target insects has been demonstrated.

Commission Regulation (EU) 2018/73 of 16 January 2018 amended Annexes II and III to Regulation (EC) No 396/2005 as regards maximum residue levels for mercury compounds. Council Directive 79/117/EEC prohibited plant protection products containing mercury compounds, authorisations were revoked and all MRLs were set at the relevant limit of determination (LOD) for mercury. With mercury-containing pesticides phased out for more than thirty years, the presence of mercury in food can be considered due to environmental contamination. It was therefore considered appropriate, after consultation, to replace the default LOD values with consensus 95th percentile environmental mercury background data in

²¹⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.018.01.0001.01.ENG&toc=OJ:L:2018:018:TOC

²¹⁵ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474202948544&uri=CELEX:02009R1107-20140630> (but see EUR-Lex for latest version)

²¹⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474199567547&uri=CELEX:32011R0540> (but see EUR-Lex for latest version)

²¹⁷ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.114.01.0008.01.ENG&toc=OJ:L:2018:114:TOC b

²¹⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.205.01.0059.01.ENG&toc=OJ:L:2017:205:TOC

Regulation 396/2005. These mercury data are: tree nuts 0,02 mg kg⁻¹; fresh herbs 0.03 mg kg⁻¹; cultivated fungi 0.05 mg kg⁻¹; wild fungi 0.50 mg kg⁻¹, except for ceps 0.90 mg kg⁻¹; oilseeds 0.02 mg kg⁻¹; teas, coffee beans, herbal infusions and cocoa beans 0.02 mg kg⁻¹; spices 0.02 mg kg⁻¹, except ginger, nutmeg, mace and turmeric 0.05 mg kg⁻¹; meat 0.01 mg kg⁻¹, except for meat of wild game animals 0.015 mg kg⁻¹ and duck meat (farmed and wild) 0.04 mg kg⁻¹; animal fat 0.01 mg kg⁻¹; edible offal 0.02 mg kg⁻¹ except for offal of wild game animals 0.025 mg kg⁻¹ and offal of wild boar 0.10 mg kg⁻¹; milk 0.01 mg kg⁻¹; and honey 0.01 mg kg⁻¹. This will enable national competent authorities to take appropriate enforcement action on the basis of realistic MRLs.²¹⁹

Commission Implementing Regulation (EU) 2018/555 of 9 April 2018 sets out the EU coordinated multiannual pesticides control programme for 2019, 2020 and 2021 to ensure compliance with maximum residue levels and to assess consumer exposure to pesticide residues in and on food of plant and animal origin. The regulation sets out the products to be sampled, a list of pesticides to be analysed and minimum sample numbers.²²⁰

In a series of linked cases, the General Court of the Court of Justice of the European Union confirmed the validity of the restrictions introduced at EU level in 2013 against the insecticides clothianidin, thiamethoxam and imidacloprid, because of the risks those substances pose to bees. However, it largely upheld the action brought by BASF and annulled the measures restricting the use of the pesticide fipronil, since they were imposed without a prior impact assessment. The judgements are summarised in a press release²²¹ and the cases were (a) T-429/13 Bayer CropScience AG and Others v Commission, (b) T-451/13 Syngenta Crop Protection AG and Others v Commission, and (c) T-584/13 BASF Agro BV and Others v Commission.²²²

2.9.1 Biocidal Products

The Biocidal Product Regulation (Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product. The regulation is frequently updated. Further information is available on the website of the European Chemicals Agency.²²³

Commission Delegated Regulation (EU) 2017/698 of 3 February 2017 amended Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012.²²⁴

2.10 Products of animal origin

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

²¹⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.013.01.0008.01.ENG&toc=OJ:L:2018:013:TOC

²²⁰ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.092.01.0006.01.ENG&toc=OJ:L:2018:092:TOC

²²¹ <https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-05/cp180068en.pdf>

²²² https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.231.01.0019.01.ENG&toc=OJ:C:2018:231:TOC

²²³ <https://echa.europa.eu/regulations/biocidal-products-regulation>

²²⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.103.01.0001.01.ENG&toc=OJ:L:2017:103:TOC

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

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

2.11 Radioactivity

Commission Implementing Regulation (EU) 2016/6 of 5 January 2016 relaxed the special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station, and repealed Implementing Regulation (EU) No 322/2014.

Commission Implementing Regulation (EU) 2017/2058 of 10 November 2017 further relaxed Regulation (EU) 2016/6 on foot of data gathered by the Japanese authorities and import controls at the EU border.²²⁵

Council Regulation (Euratom) 2016/52²²⁶ sets out maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency, and repeals Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90.

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

2.12 Transmissible spongiform encephalopathies

Transmissible Spongiform Encephalopathies, TSE, are a family of diseases occurring in man and animals and are characterised by a degeneration of brain tissue to a sponge-like appearance leading to death. The family includes diseases such as Creutzfeldt-Jakob Disease, CJD, variant Creutzfeldt-Jakob Disease, vCJD and Kuru in humans, Bovine Spongiform Encephalopathy, BSE, in cattle, Scrapie in small ruminants (sheep and goats), Chronic Wasting Disease in cervids (e.g. deer) and Transmissible Mink Encephalopathy. The commonly accepted cause of the TSE diseases is a transmissible agent called a prion (PrPres), which is an abnormal form of a protein. The framework legislation is Regulation (EC) No 999/2001.²²⁷

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 2016/1396.²²⁸

²²⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.294.01.0029.01.ENG&toc=OJ:L:2017:294:TOC

²²⁶ 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

²²⁷ http://ec.europa.eu/food/safety/biosafety/food_borne_diseases/tse_bse/index_en.htm

²²⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1396>

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.²²⁹

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.²³⁰

Commission Regulation (EU) 2017/893 of 24 May 2017 amended Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein.²³¹ Processed animal protein derived from insects and compound feed containing such processed animal protein is authorised for feeding aquaculture animals and other amendments are made.

Commission Regulation (EU) 2017/894 of 24 May 2017 amended Annexes III and VII to Regulation (EC) No 999/2001 as regards the genotyping of ovine animals.²³²

Commission Implementing Decision (EU) 2017/1396 of 26 July 2017 amended the Annex to Decision 2007/453/EC as regards country BSE status. Northern Ireland, Scotland and Poland were recognised as having a negligible BSE risk. England and Wales remain currently listed as countries with a controlled BSE risk.²³³

The Transmissible Spongiform Encephalopathies (England) Regulations 2018, coming into force on 19 July 2018 were made.²³⁴ These Regulations, which apply in England, revoke and remake with amendments the Transmissible Spongiform Encephalopathies (England) Regulations 2010 (S.I. 2010/801).

The Regulations enforce Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (“the EU TSE Regulation”). The provisions in Part 2 identify the TSE controls that are subject to enforcement under these Regulations and introduce Schedules 2 to 8. Part 3 deals with administration and enforcement.

Schedule 1 sets out the TSE requirements that include the obligations when a person has in their possession or under their control any animal suspected of being infected with a TSE. In addition the occupier of a slaughterhouse must comply with the requirement to take samples or to facilitate the taking of samples by an inspector resulting from the Secretary of State’s TSE monitoring requirements. Schedule 2 sets out the requirements for monitoring for TSE and the

²²⁹ 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

²³⁰ 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

²³¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.138.01.0092.01.ENG&toc=OJ:L:2017:138:TOC

²³² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.138.01.0117.01.ENG&toc=OJ:L:2017:138:TOC

²³³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.197.01.0009.01.ENG&toc=OJ:L:2017:197:TOC

²³⁴ <http://www.legislation.gov.uk/uksi/2018/731/contents/made>

approval of laboratories and provides for compensation. Schedule 3 provides for TSE controls and compensation for bovine animals (cattle). Schedule 4 provides for TSE controls and compensation for ovine and caprine animals (sheep and goats). Schedule 5 provides for TSE controls and compensation for animals that are not bovine, ovine, or caprine animals. Schedule 6 provides for restrictions to be placed on suspect feedingstuffs and for the slaughter of animals that have had access to unlawful feedingstuffs (the feeding to ruminants of protein derived from animals is prohibited). Schedule 7 sets out the controls for dealing with specified risk material and mechanically recovered meat. Slaughtering techniques are specified in the Schedule. The FSA are appointed as the competent authority for granting authorisations and carrying out Annex 5 duties provided for in the EU TSE Regulation. Schedule 8 deals with the export of live bovine animals and products derived from them to other Member States and to third countries. Schedule 9 contains a list of instruments that are revoked.

Commission Regulation (EU) 2018/969 of 9 July 2018²³⁵ amended Annex V to Regulation (EC) No 999/2001 on the requirements for the removal of specified risk materials (SRM) from small ruminants. SRM carries an increased risk of transmission of spongiform encephalopathies (TSE/BSE). However owing to low incidence and following detailed risk assessments it has been agreed that only the skull, including the brain and the eyes, and the spinal cord of animals over 12 months of age, or which have a permanent incisor erupted through the gum, should be considered as SRM in ovine and caprine animals. The estimation of the age of ovine and caprine animals based on dentition provides only an approximation. Other methods of age estimation evaluated and approved by the competent authority of the Member State of slaughter are permitted.

The Transmissible Spongiform Encephalopathies (Wales) Regulations 2018²³⁶, made in September 2018 and in force from 1 October 2018 revoke and remake with amendments the Transmissible Spongiform Encephalopathies (Wales) Regulations 2008. They continue to enforce Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

2.13 Toxicology

EFSA have established 'OpenFoodTox', a new database that provides access to information from over 1,650 EFSA scientific outputs about the toxicity of chemicals found in the food and feed chain. An editorial published in the EFSA Journal in January 2017 describes how to use the database.²³⁷

2.13.1 Carcinogenicity of meat and processed meat

There has long been speculation on the carcinogenicity of red meat and processed meat. Carcinogens can be produced by cooking of meat, with greatest amounts generated at high temperatures by pan-frying, grilling, or barbecuing. Meat processing such as curing and smoking can result in formation of carcinogens.

²³⁵ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.174.01.0012.01.ENG&toc=OJ:L:2018:174:TOC

²³⁶ <https://www.legislation.gov.uk/wsi/2018/968/introduction/made>

²³⁷ <http://www.efsa.europa.eu/en/press/news/170118-0>

In August 2018 the International Agency for Research on Cancer (IARC)²³⁸ published a monograph attempting to summarise research to date on this topic.²³⁹ Red meat refers to unprocessed mammalian muscle meat (e.g. beef, veal, pork, lamb) including that which may be minced or frozen. Processed meat refers to meat that has been transformed through salting, curing, fermentation, smoking or other processes to enhance flavour or improve preservation. Most processed meats contain pork or beef, but may also contain other meats including poultry and offal (e.g. liver) or meat by-products such as blood.

An IARC Monographs Working Group reviewed epidemiological evidence, animal bioassays, and mechanistic and other relevant data. The Working Group assessed more than 800 epidemiological studies that investigated the association of cancer (more than 15 types) with consumption of red meat or processed meat, including large cohorts in many countries, from several continents, with diverse ethnicities and diets.

Meat may contain residues of veterinary drugs or contaminating environmental pollutants. Meat processing, such as curing and smoking can result in the formation of carcinogenic chemicals, including N-nitroso compounds (NOCs) and polycyclic aromatic hydrocarbons (PAHs). The cooking of meat improves the digestibility, palatability, and organoleptic quality of meat; however, it can also produce carcinogens, including heterocyclic aromatic amines (HAAs) and PAHs. The amounts of these chemicals formed in cooked red meat can vary by more than a hundredfold, depending on the kind of meat and the method of cooking (temperature, time, and heating source). High-temperature cooking by frying, grilling, or barbecuing generally produces the highest amounts of these chemicals.

In this complex and difficult area definitive conclusions are difficult to arrive at. However based on the balance of evidence, and taking into account study design, size, quality, control of potential confounding, exposure assessment, and magnitude of risk, an increased risk of cancer of the colorectum was seen in relation to consumption of red meat and of processed meat. The large amount of data, strength of association, and consistency across cohort studies in different populations, including most of the larger cohort studies, makes chance, bias, and confounding unlikely as explanations for the association of consumption of processed meat with cancer of the colorectum. However, chance, bias, or confounding could not be ruled out for consumption of red meat, as no association was observed in several of the larger studies. The available evidence from a subset of studies suggested that some cooking methods used in the preparation of red meat may contribute to the observed associations.

The majority of well-designed, population-based case-control studies, from Canada, the USA, and Mexico that reported on the association with consumption of processed meat, showed increased risks for gastric cancer, which were also statistically significant in three of the studies. A published meta-analysis reported positive associations for case-control studies, and for cohort studies. Positive associations between processed meat consumption and stomach cancer were observed in several case-control and cohort studies in diverse populations. However, the modest number of studies and lack of association in the other cohort studies suggested that chance, bias, and confounding could not be ruled out.

²³⁸ <https://www.iarc.fr/>

²³⁹ IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 114 Red Meat and Processed Meat, <http://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Evaluation-Of-Carcinogenic-Risks-To-Humans/Red-Meat-And-Processed-Meat-2018>

Associations with other cancers such as prostate, lung and breast were less amenable to a short summary and readers should consult the original document for more information.

See also Section 6.4.1 for information on the toxicology of formaldehyde.

2.14 Veterinary residues

Commission Regulation (EU) No 37/2010 of 22 December 2009 deals with MRLs of veterinary medicinal products in foodstuffs of animal origin. Domestic effect is given by the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015²⁴⁰ and, in Northern Ireland, by the Animal and Animal Products (Examination for Residues and Maximum Residue Limits) (Northern Ireland) 2016 (SR 54).²⁴¹

Regulation (EU) No 37/2010 is regularly amended as regards MRLs. Further information is available from the European Medicines Agency (EMA)²⁴² and on the European Commission website.²⁴³ The latest consolidated version of Regulation 37/2010 (available on EUR-Lex) should be consulted for MRLs however there is a time-lag between amendments being made and their incorporation into the consolidated version. It is therefore best to search EUR-Lex from the date of the last amendment to ensure full coverage.

Toxicological evaluation of veterinary residues is carried out by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), an international expert scientific committee administered jointly by the FAO and the WHO.²⁴⁴

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.²⁴⁵

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).²⁴⁶

Official sampling strategy, sampling levels and frequency are set out in Annexes III and IV to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and

²⁴⁰ http://www.legislation.gov.uk/uksi/2015/787/pdfs/uksi_20150787_en.pdf

²⁴¹ http://www.legislation.gov.uk/nisr/2016/54/pdfs/nisr_20160054_en.pdf

²⁴² http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000165.jsp

²⁴³ http://ec.europa.eu/health/documents/community-register/index_en.htm

²⁴⁴ <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/>

²⁴⁵ 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

²⁴⁶ 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

residues thereof in live animals and animal products, (latest consolidated version 1 July 2013²⁴⁷). Commission Decision 98/179/EC of 23 February 1998 (latest consolidated version 1 July 2013²⁴⁸) lays down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products and includes provision, unless technically impossible or not required by national legislation, to divide each sample into at least two equivalent sub-samples each allowing the complete analytical procedure. The subdivision can take place at the sampling location or in the laboratory.

Commission Regulation (EU) 2017/880 of 23 May 2017 set out rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff, for another foodstuff derived from the same species and a maximum residue limit established for a pharmacologically active substance in one or more species for application to other species, in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council.²⁴⁹

A summary of why and how veterinary residues are controlled in food and current problems arising from technical appeals to the Government Chemist in this area was published in the June 2017 edition of the IFST house journal FS&T.²⁵⁰

2.15 Food Hygiene

Good food hygiene means controlling harmful micro-organisms which can cause serious illness. The four essential measures are (a) to control cross-contamination, (b) effective cleaning (c) thorough cooking and (d) immediate chilling after cooking. These are summarised as ‘cook, chill, clean, separate’.²⁵¹ HACCP (Hazard Analysis and Critical Control Point) is a key system that helps food business operators address food hygiene.²⁵² Food Hygiene is controlled legislatively by Food Safety and Hygiene Regulations, currently the Food Safety and Hygiene (England) Regulations 2013²⁵³ with equivalents in Wales,²⁵⁴ Scotland²⁵⁵ and Northern Ireland.²⁵⁶ These regulations identify the “EU Hygiene Regulations” as Regulation 852/2004, Regulation 853/2004, Regulation 854/2004, Regulation 2073/2005 and Regulation 2075/2005. A schedule to the UK regulations lists the means of the following hygiene measures: Decision 2006/766, Directive 2004/41, Regulation 178/2002, Regulation 852/2004, Regulation 853/2004, Regulation 854/2004, “Regulation 882/2004”, “Regulation 1688/2005”, “Regulation 2073/2005”, “Regulation 2074/2005”, Regulation 2075/2005, Regulation 1020/2008, Regulation 1021/2008, Regulation 596/2009, Regulation 669/2009, Regulation 1169/2011, Regulation 28/2012 and Regulation 1079/2013.

EU Regulation No. 2073/2005 on microbiological criteria for foods (as amended by EU Regulation No. 1441/2007) complements the food hygiene legislation and applies to all food businesses involved in the production and handling of food.²⁵⁷ Guidance on microbiological criteria is available from Public Health England²⁵⁸ and from IFST on aspects such as Shigatoxin-

²⁴⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498122962393&uri=CELEX:01996L0023-20130701>

²⁴⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498134918739&uri=CELEX:01998D0179-20130701>

²⁴⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.135.01.0001.01.ENG&toc=OJ:L:2017:135:TOC

²⁵⁰ Walker M. and Gray L. (2017), Veterinary residues in food, FS&T, 31, 23-27 <http://fstjournal.org/features/31-2/veterinary-residues>

²⁵¹ <https://www.food.gov.uk/business-industry/food-hygiene>

²⁵² <https://www.food.gov.uk/business-industry/food-hygiene/haccp>

²⁵³ <http://www.legislation.gov.uk/uksi/2013/2996/note/made>

²⁵⁴ Food Hygiene (Wales) Regulations 2006 with many subsequent amendments

²⁵⁵ Food Hygiene (Scotland) Regulations 2006 with many subsequent amendments

²⁵⁶ The Food Hygiene Regulations (Northern Ireland) 2006 with many subsequent amendments

²⁵⁷ <https://www.food.gov.uk/business-industry/guidancenotes/hygguid/microbiolreg>

²⁵⁸ PHE, 2009, Ready-to-eat foods: microbiological safety assessment guidelines

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

producing *E. coli*, fresh produce safety, foodborne viral infections, campylobacter, cyclospora, and cryptosporidium.²⁵⁹

Commission Regulation (EU) 2017/1495 of 23 August 2017²⁶⁰ amended Regulation (EC) No 2073/2005 as regards *Campylobacter* in broiler carcasses.

Regulation (EC) No 852/2004 of 29 April 2004²⁶¹ on the hygiene of foodstuffs imposes responsibilities and duties on food business operators including HACCP, temperature control, maintenance of a cold chain and sampling and analysis.

Food Hygiene (Amendment) Regulations made in England, Wales, Scotland and Northern Ireland came into force in October 2016 and made various amendments to provide for the execution and enforcement of Commission Implementing Regulation (EU) 2015/1375 laying down specific rules on official controls for *Trichinella* in meat.²⁶²⁻²⁶⁵

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 2016.²⁶⁶ The incident attracted considerable publicity.

The Commission has produced a guidance document addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene (2017/C 163/01).²⁶⁷

Commission Decision (EU) 2017/1583 of 1 September 2017 specified, pursuant to Directive 2006/7/EC of the European Parliament and of the Council, EN ISO 17994:2014 as the standard on the equivalence of microbiological methods, (notified under document C(2017) 5843). This is in relation to Directive 2006/7/EC on the management of bathing water quality. EN ISO 17994:2014 replaces an outdated standard and introduces technical updates (e.g. terminology, clearer specifications, and addition of a new Annex on technical calculations).²⁶⁸

On 11 October 2017 the FSA announced a change to its advice about eating eggs – infants, children, pregnant women and elderly people can now safely eat raw or lightly cooked eggs that are produced under the British Lion Code of Practice. The revised advice, based on the scientific evidence assessed by the Advisory Committee on the Microbiological Safety of Food (ACMSF), means that people vulnerable to infection or who are likely to suffer serious symptoms from food poisoning can now safely eat raw or lightly cooked hen eggs or foods containing them.²⁶⁹

The World Health Organization has published guidance on the selection and application of methods for the detection and enumeration of human-pathogenic halophilic vibrio spp. in seafood. This considers the range of potential methods from culture based to molecular

²⁵⁹ <http://www.ifst.org/knowledge-centre/information-statements>

²⁶⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.218.01.0001.01.ENG&toc=OJ:L:2017:218:TOC

²⁶¹ Latest consolidated version 20.04.2009, <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498136347793&uri=CELEX:02004R0852-20090420>

²⁶² The Food Safety and Hygiene (England) (Amendment) Regulations 2016

<http://legislation.data.gov.uk/ukxi/2016/868/made/data.pdf>

²⁶³ The Food Hygiene (Wales) (Amendment) Regulations 2016, <http://www.legislation.gov.uk/cy/wsi/2016/845/made>

²⁶⁴ The Food Hygiene (Scotland) Amendment Regulations 2016

http://www.legislation.gov.uk/ssi/2016/260/pdfs/ssi_20160260_en.pdf

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

²⁶⁶ <http://www.hps.scot.nhs.uk/pubs/detail.aspx?id=3200>

²⁶⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.163.01.0001.01.ENG&toc=OJ:C:2017:163:TOC

²⁶⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1512389494729&uri=CELEX:32017D1583>

²⁶⁹ <http://webarchive.nationalarchives.gov.uk/20171207160203/https://www.food.gov.uk/news-updates/news/2017/16597/new-advice-on-eating-runny-eggs>

biological, and proposes the use of performance characteristics to select the most appropriate method according to the potential end use of the data generated, for example, harvest area monitoring, post-harvest process verification, end product monitoring, and outbreak investigation. Aspects of data requirements that could support national and regional risk assessments are also addressed.²⁷⁰

Commission Implementing Regulation (EU) 2017/2369 of 18 December 2017 extended to 31 December 2021 the provisions of Implementing Regulation (EU) No 743/2013, introducing protective measures on imports of bivalve molluscs from Turkey intended for human consumption. The measures include a ban on importation of live and chilled bivalve molluscs and testing for *Escherichia coli* and marine biotoxins in all consignments of frozen bivalve molluscs. The extension arose from deficiencies in the official control system, notably in the performance of laboratories.²⁷¹

Pursuant to Article 9 of Regulation 852/2004 the Commission has published²⁷² the 'European Guide for Good Hygiene Practices in the production of artisanal cheese and dairy products',²⁷³ authored by the Farmhouse and Artisan Cheese & Dairy Producers European Network (FACE network). This is one of a suite of guidance available on the Commission website.²⁷⁴

Commission Implementing Regulation (EU) 2018/307 of 28 February 2018 extended the special guarantees concerning *Salmonella* spp. laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council to meat derived from broilers (*Gallus gallus*) intended for Denmark. Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators, with certain special guarantees for certain food of animal origin intended for the Finnish and Swedish markets. Accordingly, food business operators intending to place meat from specified animals on the market in those Member States must comply with certain rules in respect of Salmonella. Furthermore, consignments of such meat are to be accompanied by a trade document stating that a microbiological test has been carried out with negative results in accordance with EU legislation.²⁷⁵

The United Nations, Economic Commission for Europe, Inland Transport Committee, has published an 'Agreement on the international carriage of perishable foodstuffs and the special equipment to be used for such carriage (ATP): as amended on 6 January 2018'. The agreement stipulates such matters as refrigeration equipment.²⁷⁶

Commission Implementing Decision (EU) 2018/935 of 28 June 2018²⁷⁷ amended Implementing Decision 2014/88/EU which temporarily suspended imports from Bangladesh of Betel leaves, following a high number of notifications issued to the Rapid Alert System for Food and Feed (RASFF) due to the presence of a wide range of *Salmonella* strains. Despite action by the authorities in Bangladesh the situation has not improved sufficiently to remove the import ban and the amending Decision extends the ban until 30 June 2020.

²⁷⁰ http://www.who.int/foodsafety/publications/mra_22/en/

²⁷¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.337.01.0026.01.ENG&toc=OJ:L:2017:337:TOC

²⁷² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.440.01.0001.01.ENG&toc=OJ:C:2017:440:TOC

²⁷³ https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_guidance_artisanal-cheese-and-dairy-products_en.pdf

²⁷⁴ https://ec.europa.eu/food/safety/biosafety/food_hygiene/guidance_en

²⁷⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.060.01.0005.01.ENG&toc=OJ:L:2018:060:TOC

²⁷⁶ https://www.unece.org/fileadmin/DAM/trans/main/wp11/ATP_publication/2017/ATP_E_ECE_TRANS_271_WEB.pdf

²⁷⁷ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.165.01.0040.01.ENG&toc=OJ:L:2018:165:TOC

2.15.1 Enterohemorrhagic *Escherichia coli* – seeds and sprouted seeds

The Enterohemorrhagic *Escherichia coli* (EHEC) crisis of 2011 focused mainly in Germany with hemolytic-uremic syndrome (HUS) and bloody diarrhoea infecting almost 4,000 people and resulting in 53 deaths.²⁷⁸ Following EFSA's opinion²⁷⁹ on the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds new EU legislation was brought in to supplement general food safety requirements in Regulation 178/2002 and hygienic production covered by Regulation 852/2004. These were Commission Implementing Regulation (EU) No 208/2013 on traceability requirements for sprouts and seeds intended for the production of sprouts, Commission Regulation (EU) No 209/2013 (amending Regulation (EC) No 2073/2005) on microbiological criterion for sprouts, Commission Regulation (EU) No 210/2013 on the approval of establishments producing sprouts and Commission Regulation (EU) No 211/2013 (amended by Commission Regulation (EU) No 704/2014) on certification requirements for imports of sprouts and seeds for sprouting into the EU. The requirements of the above regulations and comprehensive instructions on hygienic practices for the safe production of sprouts and seeds for sprouting are included in a guideline produced by the European Sprouted Seeds Association and published by the Commission in the Official Journal in July 2017 under the reference 2017/C 220/03.²⁸⁰

2.15.2 Food hygiene rating schemes

Food Hygiene Rating Schemes help consumers choose where to eat out or shop for food by giving them information about the hygiene standards in restaurants, takeaways and food shops.²⁸¹

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)²⁸² which came into force on 28 November 2016 and The Food Hygiene Rating Act (Northern Ireland) 2016.²⁸³ In Wales the regulation applies to establishments which supply takeaway food and requires a conspicuous notice in Welsh and English to indicate the availability of the business food hygiene rating. Receipts from fixed penalties can only be used for the purposes of the Public Health (Wales) Act 2017²⁸⁴ and regulations made under it. The Food Hygiene Rating Regulations (Northern Ireland) 2016 no. 313²⁸⁵ and the Food Hygiene Rating (Transitional Provisions) Order (Northern Ireland) 2016 no. 314²⁸⁶ 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.²⁸⁷ 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

²⁷⁸ http://www.bfr.bund.de/en/ehec_outbreak_2011-186689.html

²⁷⁹ <http://www.efsa.europa.eu/en/efsajournal/pub/2424>

²⁸⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.220.01.0029.01.ENG&toc=OJ.C:2017:220:TOC

²⁸¹ <https://www.food.gov.uk/safety-hygiene/food-hygiene-rating-scheme>

²⁸² http://www.legislation.gov.uk/wsi/2016/429/pdfs/wsi_20160429_mi.pdf

²⁸³ Food Hygiene Rating Act (Northern Ireland) 2016, Ch 3 <http://origin-www.legislation.gov.uk/nia/2016/3/enacted>

²⁸⁴ <http://www.legislation.gov.uk/anaw/2017/2/contents/enacted>

²⁸⁵ <http://www.legislation.gov.uk/nisr/2016/313/made>

²⁸⁶ <http://www.legislation.gov.uk/nisr/2016/314/made>

²⁸⁷ <http://www.legislation.gov.uk/nisr/2016/328/made/data.pdf>

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 made²⁸⁸ coming into force when made and establishing a fee for re-rating an establishment of £150.00 and a fixed penalty of £200.00 if, without reasonable excuse, no valid (or an invalid) food hygiene rating is displayed (or, where appropriate, made available online).

2.16 Water for human consumption

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

The primary EU law on supplied water is Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, alongside Directive 2009/54/EC on the exploitation and marketing of natural mineral waters²⁸⁹ (recast)²⁹⁰ and Directive 2003/40/EC establishing a list of parameters, 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.²⁹¹

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

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015^{292, 293} amended the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007 ("the 2007 Regulations") by implementing, in relation to spring water and drinking water in a bottle, Council Directive 2013/51/Euratom laying down the requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (OJ L 296, 7.11.13, p.12). Regulation 3 makes consequential amendments to the interpretation provisions in regulation 2 of the 2007 Regulations. Regulation 4 amends regulation 16 of the 2007 Regulations to specify the monitoring and sampling requirements required by Food Authorities. Similar legislation has been enacted in Wales by the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015²⁹⁴ (SI 1867, W274) and in Northern Ireland with the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2015²⁹⁵ (SR 365).

²⁸⁸ http://www.legislation.gov.uk/nistr/2016/425/pdfs/nistr_20160425_en.pdf

²⁸⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1453734625466&uri=CELEX:32009L0054>

²⁹⁰ Which repeals and replaces Directive 80/777/EEC.

²⁹¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1453734764128&uri=CELEX:32003L0040>

²⁹² http://www.legislation.gov.uk/ssi/2015/363/pdfs/ssi_20150363_en.pdf

²⁹³ http://www.legislation.gov.uk/ssi/2015/363/pdfs/ssics_20150363_en.pdf correction slip

²⁹⁴ http://www.legislation.gov.uk/wsi/2015/1867/pdfs/wsi_20151867_mi.pdf

²⁹⁵ http://www.legislation.gov.uk/nistr/2015/365/pdfs/nistr_20150365_en.pdf

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015 (correction slip) of 25 May 2017 made correction to the Welsh language version of the regulations.²⁹⁶

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2017, made on 6 September 2017 and brought into force on 27 October 2017 again amended the 2007 Regulations as a result of amendments to their European measures. Commission Directive (EU) 2015/1787 amended Annexes II and III to Council Directive 98/83/EC as regards the quality of water intended for human consumption. These Regulations transpose the provisions of the Directive only in respect of bottled drinking water which is marketed as spring water or bottled drinking water. The remaining provisions of the Directive are implemented by the Public Water Supplies (Scotland) Amendment Regulations 2017 and the Water Intended for Human Consumption (Private Supplies) (Scotland) Regulations 2017. The Regulations remove the obligations on food authorities to check monitor and to audit monitor spring water and bottled drinking water in regulation 16 and schedules 9 to 11 of the 2007 Regulations. They thus clarify enforcement provisions, in particular to remove obligations on food authorities to monitor substances such as ammonia and oxidisability in spring water and bottled water that relate more properly to non-bottled water supplies.²⁹⁷ These regulations have now been amended many times and appear to be a prime candidate for consolidation.

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2017,²⁹⁸ made 17 September 2017, and in force on 27 October 2017, amended the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015. They implement the amended monitoring requirements for spring water and bottled drinking water mentioned above in the Scottish 2017 amending Regulations (Welsh regulations 8 and 14). They also allow natural mineral water and spring water that has been subjected to fluoride removal treatment or ozone-enriched air treatment in a non-EEA State to be sold in Wales if the treatments are suitably authorised (regulations 3, 9 and 10). They clarify that natural mineral water and spring water extracted otherwise than in Wales may only be sold in Wales if it complies with the requirements as described in the 2015 Regulations in relation to exploitation (in the case of natural mineral water), treatments and additions, and bottling and labelling requirements (regulations 4 and 7). The rules on treatments and additions do not prevent spring water from being used in the manufacture of soft drinks (regulation 5). The Regulations prohibit the advertising of spring water in a way that is liable to cause the water to be confused with a natural mineral water, and prohibit the use of “mineral water”, “dŵr mwynol”, or its equivalent in any other language, in the advertising of spring water (regulation 6). The exemption period (5 years) from monitoring for certain radiological substances is clarified (regulation 15). Lastly, several errors in previous regulations are corrected.

In October 2017 the Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) Regulations (Northern Ireland) 2017²⁹⁹ amended the parent 2015 Northern Ireland regulations. In so doing and in parallel with provisions in Scotland and Wales they implement Commission Directive (EU) 2015/1787 which amends Annexes II and III to Council Directive 98/83/EC. New definitions of “fluoride removal treatment” and “ozone-enriched air treatment” are given, it is clarified that natural mineral water produced outside of Northern Ireland is required to comply with the relevant requirements of the 2015 Regulations when sold in Northern Ireland and ‘spring water’ can be used in the manufacture of soft drinks. The advertising of spring water must

²⁹⁶ http://www.legislation.gov.uk/wsi/2015/1867/pdfs/wsics_20151867_mi.pdf

²⁹⁷ <http://www.legislation.gov.uk/ssi/2017/287/contents/made>

²⁹⁸ <http://www.legislation.gov.uk/wsi/2017/935/contents/made>

²⁹⁹ <http://www.legislation.gov.uk/nisr/2017/201/contents/made>

not cause confusion with a natural mineral water. A person may not sell as spring water, water that has been subject to treatment or addition regardless of where that treatment or addition took place. Similar provisions on checking and audit monitoring for spring water and bottled drinking water as well as certain radiological provisions and corrections as in Scotland and Wales are introduced.

The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) (Amendment) Regulations 2018³⁰⁰ were made on 7 March 2018, coming into force on 6 April 2018. They amend the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007 in similar terms as in Scotland, Wales and Northern Ireland (see above). Thus the provisions of Council Directive 2013/51/Euratom and Commission Directive (EU) 2015/1787 are dealt with. So far as the former applies to public and private water supplies, the measures are implemented in England by the Water Supply (Water Quality) Regulations 2016,³⁰¹ as amended, and the Private Water Supplies (England) Regulations 2016,³⁰² as amended; both will be amended to implement the provisions of Commission Directive (EU) 2015/1787 in England in similar terms as in Wales (see below). The Regulations also amend application of provisions in the Food Safety Act 1990 including enabling an improvement notice to be served requiring compliance with specified provisions of the 2007 Regulations. Failure to comply with an improvement notice is an offence. The Regulations also make minor amendments to the 2007 Regulations, including updating definitions.

Commission Directive 2015/1787³⁰³ 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)³⁰⁴ 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.

³⁰⁰ <http://www.legislation.gov.uk/ukxi/2018/352/note/made>

³⁰¹ <http://www.legislation.gov.uk/ukxi/2016/614/contents/made>

³⁰² <http://www.legislation.gov.uk/ukxi/2016/618/contents/made>

³⁰³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.260.01.0006.01.ENG

³⁰⁴ <http://www.assembly.wales/laid%20documents/sub-ld10651/sub-ld10651-e.pdf>

The Water Supply (Water Quality) Regulations 2016, 614,³⁰⁵ enabling power: Water Industry Act 1991, and European Communities Act 1972 came into force on 27 June 2016. It affects:

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

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

Parallel regulations, the Private Water Supplies (England) Regulations 2016, SI 618, for private supplies were made, brought into force 27 June 2016.³⁰⁶ They revoke and replace the Private Water Supplies Regulations 2009 (SI 2009/3101).

The Public and Private Water Supplies (Miscellaneous Amendments) (Scotland) Regulations 2017 were made in October 2017 brought into force 26 October 2017. These make amendments pursuant to the further implementation of Council Directive 98/83/EC on the quality of water intended for human consumption including, in particular, amendments made by Commission Directive (EU) 2015/1787 amending Annexes II and III to the Directive and Council Directive 2013/51/EURATOM with regard to radioactive substances in water intended for human consumption.³⁰⁷

Similar provisions were made in October 2017 in Northern Ireland by the Private Water Supplies Regulations (Northern Ireland) 2017³⁰⁸ and the Water Supply (Water Quality) Regulations (Northern Ireland) 2017,³⁰⁹ and in Wales by the Private Water Supplies (Wales) Regulations 2017.³¹⁰

In May 2018 a list of natural mineral waters recognised by Iceland and Norway was published.³¹¹

³⁰⁵ http://www.legislation.gov.uk/ukxi/2016/614/pdfs/ukxi_20160614_en.pdf

³⁰⁶ <http://www.legislation.gov.uk/ukxi/2016/618/contents/made>

³⁰⁷ <http://www.legislation.gov.uk/ssi/2017/321/contents/made>

³⁰⁸ <http://www.legislation.gov.uk/nisr/2017/211/made>

³⁰⁹ <http://www.legislation.gov.uk/nisr/2017/212/made>

³¹⁰ <http://www.legislation.gov.uk/wsi/2017/1041/made>

³¹¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.155.01.0009.01.ENG&toc=OJ:C:2018:155:TOC

2.17 Psychoactive substances

The Psychoactive Substances Act 2016 received Royal Assent on 28 January 2016. The act applies across the UK and came into force on 26 May 2016.³¹²

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 available³¹³ as well as Home Office guidance for local authorities on taking action against “head shops” selling psychoactive substances,³¹⁴ and Home Office guidance for retailers.³¹⁵ Guidance is available from the Crown Prosecution Service on psychoactive substances in general and on assessing whether or not a substance is psychoactive. It is suggested that the suspected substance must be submitted to a Forensic Service Provider for analysis and identification. Separately, an expert witness should be asked to give an opinion as to whether the identified substance was capable of having a psychoactive effect based on analysis of the identified substance in a laboratory. That opinion will be based on a chemical reference standard produced as a result of that substance having been tested previously. Further detail about psychoactivity testing is set out in the Home Office's Forensic Strategy³¹⁶ 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 2016,³¹⁷ the Psychoactive Substances Act 2016 (Commencement) Regulations 2016³¹⁸ and the Magistrates' Courts (Psychoactive Substances Act 2016) (Transfer of Proceedings) Rules 2016.³¹⁹

The Psychoactive Substances Act 2016 (correction slip) noted Schedule 5, paragraph 8(2): “1A” should read “1ZA”.³²⁰

³¹² <http://www.legislation.gov.uk/ukpga/2016/2/contents/enacted>

³¹³ <https://www.gov.uk/government/collections/psychoactive-substances-bill-2015>

³¹⁴ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/410961/Guidance_for_local_authorities_on_taking_action_against_10.03_15.pdf

³¹⁵ <https://www.gov.uk/government/publications/psychoactive-substances-act-guidance-for-retailers/psychoactive-substances-act-2016-guidance-for-retailers>

³¹⁶ <https://www.gov.uk/government/publications/circular-0042016-psychoactive-substances-act-2016>

³¹⁷ <http://www.legislation.gov.uk/uksi/2016/554/regulation/2/made>

³¹⁸ <http://www.legislation.gov.uk/uksi/2016/553/contents/made>

³¹⁹ <http://www.legislation.gov.uk/uksi/2016/546/made>

³²⁰ http://www.legislation.gov.uk/ukpga/2016/2/pdfs/ukpgacs_20160002_en.pdf

Regulation (EU) No 1307/2013³²¹ establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy (Article 32(6)) provides that in order to prevent support payments being granted for illegal crops, areas used for the production of hemp may only be eligible if the varieties used have a tetrahydrocannabinol, THC, content in year on year testing not exceeding 0.2%.

Commission Delegated Regulation (EU) 2017/1155 of 15 February 2017, published in June 2017 amended Delegated Regulation (EU) No 639/2014 as regards the control measures relating to the cultivation of hemp with regard to farm support payments (and other farm support measures not relevant to food or feed legislation).³²²

Commission Recommendation (EU) 2016/2115³²³ 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.³²⁴

Commission Implementing Regulation (EU) 2017/1172 of 30 June 2017³²⁵ amended Implementing Regulation (EU) No 809/2014 as regards the control measures relating to the cultivation of hemp to allow submission later in the year of official seed labels.

Council Implementing Decision (EU) 2017/1774 of 25 September 2017 imposed control measures as a new psychoactive substance on acryloylfentanyl, (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide). Acryloylfentanyl is a synthetic opioid structurally similar to fentanyl, a controlled substance widely used in medicine as an adjunct to general anaesthesia during surgery and for pain management. The available data suggest that acryloylfentanyl is a potent and long-lasting antinociceptive agent (reducing sensitivity to painful stimuli). Three Member States have collectively reported 47 deaths associated with acryloylfentanyl. In at least 40 deaths, acryloylfentanyl was the cause of death or is likely to have been a contributing cause of death. In addition, more than 20 acute intoxications suspected to be due to acryloylfentanyl have been reported. The United Kingdom is not bound by Decision 2005/387/JHA under which the above Decision is made.³²⁶

For similar reasons Council Implementing Decision (EU) 2017/2170 of 15 November 2017³²⁷ imposed control measures as a new psychoactive substance on N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl).

The Commission signalled its intention to the adopt a Directive of the European Parliament and of the Council amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA.³²⁸ This was done by Directive (EU) 2017/2103³²⁹ of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in

³²¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1499100367442&uri=CELEX:02013R1307-20150603>

³²² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.167.01.0001.01.ENG&toc=OJ:L:2017:167:TOC

³²³ 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

³²⁴ <https://www.efsa.europa.eu/en/efsajournal/pub/4141>

³²⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.170.01.0087.01.ENG&toc=OJ:L:2017:170:TOC

³²⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.251.01.0021.01.ENG&toc=OJ:L:2017:251:TOC

³²⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.306.01.0019.01.ENG&toc=OJ:L:2017:306:TOC

³²⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.359.01.0001.01.ENG&toc=OJ:C:2017:359:TOC

³²⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.305.01.0012.01.ENG&toc=OJ:L:2017:305:TOC

order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA.

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

In November 2017 the Court of Appeal (Criminal Division) heard appeals on convictions of possessing a psychoactive substance, nitrous oxide, with intent to supply contrary to Section 7 of the Psychoactive Substances Act 2016. The grounds of appeal focused on nitrous oxide as a medicinal product and the exemption in the Psychoactive Substances Act for medicinal products as defined in the Human Medicines Regulations 2012. The court of appeal held that nitrous oxide could not be regarded as a medicinal product when used in the circumstances in which the applicants were found to possess it. Application for permission to appeal was refused.³³⁰ See also the Judgment of the Court (Fourth Chamber) of 10 July 2014 which found Article 1(2)(b) of Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC must be interpreted as not covering substances, such as those at issue in the main proceedings, which produce effects that merely modify physiological functions but which are not such as to have any beneficial effects, either immediately or in the long term, on human health, are consumed solely to induce a state of intoxication and are, as such, harmful to human health.³³¹ I am indebted to 'Lexology'³³² for an alert to the above cases.

2.18 Herbal products and medicines

Herbal medicine has been practised in many countries for centuries with particularly strong and established traditions in some Asian countries, notably in China and India but also in Europe including the UK. In the UK, use of herbal medicines is common and it is estimated that up to 20% of the population use herbal products at some time in their lives.³³³ 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.³³⁴ 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.³³⁵ A list of herbal substances, preparations and combinations for use in traditional herbal medicinal products has been established by Commission Decision 2008/911/EC of 21 November 2008.³³⁶ This list is periodically updated; see for example (non-exhaustively) Commission Implementing Decision (EU) 2016/1659 of 13 September 2016³³⁷ 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

³³⁰ Neutral Citation Number: [2017] EWCA Crim 1743, Case No: 201704033 B5, 201704131 B2, 201704393 C3 & 201704176 C5, [http://www.bailii.org/cgi-bin/format.cgi?doc=/ew/cases/EWCA/Crim/2017/1743.html&query=\(nitrous\)+AND+\(oxide\)+AND+\(psychoactive\)](http://www.bailii.org/cgi-bin/format.cgi?doc=/ew/cases/EWCA/Crim/2017/1743.html&query=(nitrous)+AND+(oxide)+AND+(psychoactive))

³³¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62013CA0358>

³³² <https://www.lexology.com/>

³³³ Walker, D. R. (2015), Report on the Regulation of Herbal Medicines and Practitioners, 26 March 2015, http://www.dcs-science.net/Report_on_Regulation_of_Herbal_Medicines_and_Practitioners.pdf (Accessed 17.09.2016)

³³⁴ Directive 2001/83/EC <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474128484290&uri=CELEX:02001L0083-20121116>

³³⁵ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474128379997&uri=CELEX:32004L0024>

³³⁶ http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm

³³⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1659>

traditional herbal medicines is updated regularly.³³⁸ A list of banned or restricted herbal products, including for example aconite, belladonna, kava-kava and ragwort, is available.³³⁹

Periodic assessment of herbal products takes place, for example recently the International Agency for Research on Cancer, IARC, of the WHO published an evaluation of carcinogenic risks to humans of some drugs and herbal medicines. Whole leaf extract of aloe vera, ginkgo biloba extract, goldenseal root powder, kava extract and the pulegone component of pennyroyal oils were classified in IARC Group 2B (possibly carcinogenic to humans).^{340, 341}

Commission Implementing Decision (EU) 2018/133 of 24 January 2018 amended Decision 2008/911/EC to add valerian, *Valeriana officinalis* L. (powdered herb and various listed extracts and tinctures) to the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established by Decision 2008/911/EC. Uses, contraindications, effects on ability to drive and use machines and undesirable effects, including in overdose, are given.³⁴² A correction of the title ('establishing' in place of 'shing') was issued.³⁴³

Similarly Commission Implementing Decision (EU) 2018/134 of 24 January 2018 amended Decision 2008/911/EC to add Ironwort, *Sideritis scardica* Griseb. to the herbal list.³⁴⁴

3 Consumer choice

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

3.1 Food labelling

The primary legislation is now Regulation 1169/2011³⁴⁵ 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.³⁴⁶ Domestic implementation is effected in England by the Food Information Regulations (SI 2014 No 1855),³⁴⁷ in Northern Ireland by the Food Information Regulations (Northern Ireland) 2014 (SR 2014 No 223)³⁴⁸ and, in Wales the Food Information Regulations (Wales) 2014 (SI 2014 No 2303, W227).³⁴⁹ In Scotland implementation is by the Food Information Regulations (Scotland) 2014 (SSI 312)³⁵⁰ which were amended in December 2015 by the Food Information (Miscellaneous Amendments) (Scotland) Regulations 2015 (SSI 410).³⁵¹ These make a set of small drafting amendments, for example clarifying aspects of the labelling of "alcohol-free", "dealcoholized" and "low alcohol" drinks.

³³⁸ <https://www.gov.uk/government/publications/herbal-medicines-granted-a-traditional-herbal-registration-thr>

³³⁹ <https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients>

³⁴⁰ <http://monographs.iarc.fr/ENG/Monographs/vol108/mono108.pdf>

³⁴¹ Grosse et al. (2013), Carcinogenicity of some drugs and herbal products, *The Lancet Oncology*, 14, 807-808,

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

³⁴² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.022.01.0036.01.ENG&toc=OJ:L:2018:022:TOC

³⁴³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.038.01.0042.01.ENG&toc=OJ:L:2018:038:TOC

³⁴⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.022.01.0041.01.ENG&toc=OJ:L:2018:022:TOC

³⁴⁵ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF>

³⁴⁶ <http://www.reading.ac.uk/foodlaw/label/links.htm>

³⁴⁷ http://www.legislation.gov.uk/ukxi/2014/1855/pdfs/ukxi_20141855_en.pdf

³⁴⁸ http://www.legislation.gov.uk/nisr/2014/223/pdfs/nisr_20140223_en.pdf

³⁴⁹ http://www.legislation.gov.uk/wsi/2014/2303/pdfs/wsi_20142303_mi.pdf

³⁵⁰ http://www.legislation.gov.uk/ssi/2014/312/pdfs/ssi_20140312_en.pdf

³⁵¹ http://www.legislation.gov.uk/ssi/2015/410/pdfs/ssi_20150410_en.pdf

Information is available on the Commission website.³⁵² Guidance on nutrition labelling is also available on the Commission website.³⁵³

On 8 June 2018 the Commission issued a Q&A notice (2018/C 196/01) on the application of Regulation (EU) No 1169/2011 intended to assist food business operators and national authorities in the application of the Regulation by providing answers to a series of questions which were raised after the entry into force of the Regulation. The Q&A gives general advice with some examples on general labelling, fair information practices, availability and placement of mandatory food information, presentation of mandatory food information and legibility, mandatory particulars (Article 9 and Section 2 of the Regulation), additional mandatory particulars for specific types or categories of foods, nutrition declarations, and food supplements.³⁵⁴

See also Section 3.3.7 on Regulation (EU) No 1308/2013 on a common organisation of the markets in agricultural products and in particular a case in the European Court that precludes the terms 'milk' and 'milk product' being applied to plant based liquids.

3.1.1 Animal welfare

Animal welfare is a topic that has gained considerable interest, including via labelling, although salience varies. See Section 5.2 for the establishment of a European Union Reference Centre for Animal Welfare.

The Animal Welfare Act 2006 makes owners and keepers responsible for ensuring that the welfare needs of their animals are met, i.e. that they have a suitable environment, are fed an appropriate diet and are protected from pain, injury, suffering and disease. A revised code of practice (CoP) for the welfare of meat chickens and meat breeding chickens was published by Defra in March 2018.³⁵⁵ The CoP was brought in by the Code of Practice for the Welfare of Meat Chickens and Meat Breeding Chickens (Appointed Day and Revocation) (England) Order 2018.³⁵⁶

The Mandatory Use of Closed Circuit Television in Slaughterhouses (England) Regulations 2018 were introduced following stalled uptake of a voluntary scheme, a report by The Farm Animal Welfare Committee, and widespread concern following several well publicised cases of animal welfare abuse in slaughterhouses. The main obligations are in force from 4 May 2018 with administrative and enforcement provisions from 5 November 2018. The regulations make provision complementary to EU Regulation 1099/2009 on the protection of animals at the time of killing and the Welfare of Animals at the Time of Killing (England) Regulations 2015. The requirements are on operators of slaughterhouses ("business operators") in England to install and operate a closed circuit television (CCTV) system in all areas where live animals are present. CCTV footage and associated data must be retained for a period of 90 days.³⁵⁷

Following a consultation³⁵⁸ the Code of Practice for the Welfare of Laying Hens and Pullets (Appointed Day and Revocation) (England) Order 2018³⁵⁹ was made, appointing 8 August 2018

³⁵² https://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation_en

³⁵³ http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm

³⁵⁴ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.196.01.0001.01.ENG&toc=OJ:C:2018:196:TOC

³⁵⁵ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/694013/meat-chicken-code-march2018.pdf

³⁵⁶ http://www.legislation.gov.uk/uksi/2018/303/pdfs/uksi_20180303_en.pdf

³⁵⁷ <https://www.legislation.gov.uk/uksi/2018/556/contents/made>

³⁵⁸ <https://www.gov.uk/government/consultations/animal-welfare-updating-the-code-of-practice-for-the-welfare-of-laying-hens>

³⁵⁹ <http://www.legislation.gov.uk/uksi/2018/859/contents/made>

as the day on which the Code of Practice (CoP) for the Welfare of Laying Hens and Pullets comes into force in England. The previous CoP is revoked. The CoP provides updated and improved guidance to owners and keepers of laying hens and pullets on how to comply with the relevant farm animal welfare legislation and how to practise good standards of stockmanship to help enhance the welfare of their animals, in line with the most recent scientific, veterinary and husbandry advice.³⁶⁰

The Court of Justice of the European Union, CJEU, gave a preliminary ruling³⁶¹ confirming the validity of Article 4(4) of Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing read together with Article 2(k) thereof. The referral to the CJEU was made in proceedings between various Muslim associations and umbrella organisations of mosques active in the Vlaams Gewest (Flemish Region, Belgium) concerning the decision adopted by a Flemish Government Minister no longer to authorise, from 2015 onwards, the ritual slaughter of animals without stunning in temporary slaughterhouses in the communes of that region during the Muslim Feast of Sacrifice. The ruling rehearses the relevant law and circumstances, including those of slaughter, confirmed the validity of the questioned articles and noted that these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court.³⁶²

3.1.2 Country of origin labelling

The Country of Origin of Certain Meats (England) Regulations 2015 (SI 518)³⁶³ 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.³⁶⁴

Similar legislation has been enacted in Northern Ireland through The Country of Origin of Certain Meats Regulations (Northern Ireland) 2015³⁶⁵ (SR 321) and in Wales by the Country of Origin of Certain Meats (Wales) Regulations 2015³⁶⁶ (SI 1591, W177).

Commission Implementing Regulation (EU) 2018/775 of 28 May 2018 set out rules for indicating the country of origin or place of provenance of the primary ingredient of a food pursuant to Article 26(3) of Regulation 1169/2011 *on the provision of food information to consumers*. The regulation deals with labelling where the country of origin or place of provenance of a food is given by any means such as statements, pictorial presentation, symbols or terms, referring to places or geographical areas. Geographic terms which literally indicate origin but whose common understanding is not such are exempted (e.g. Bolognese sauce). The regulation does not apply to geographical indications protected under Regulation 1151/2012, Regulation 1308/2013, Regulation 110/2008 or Regulation 251/2014 (see Section 3.1.8) or protected pursuant to international agreements, nor to registered trademarks where the latter constitute an origin indication, pending the adoption of specific rules concerning the application of Article 26(3) to such indications. ‘Primary ingredient’ means an ingredient or ingredients of a food that represent more than 50% of that food or which are usually associated with the name of the food by the consumer and for which in most cases a quantitative indication is required (Reg. 2 (q), Regulation

³⁶⁰ <https://www.gov.uk/government/publications/poultry-on-farm-welfare>

³⁶¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.259.01.0005.02.ENG&toc=OJ:C:2018:259:TOC

³⁶² <https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX%3A62016CJ0426>

³⁶³ http://www.legislation.gov.uk/ukxi/2015/518/pdfs/ukxi_20150518_en.pdf

³⁶⁴ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2015>

³⁶⁵ http://www.legislation.gov.uk/nisr/2015/321/pdfs/nisr_20150321_en.pdf

³⁶⁶ http://www.legislation.gov.uk/wsi/2015/1519/pdfs/wsi_20151519_mi.pdf

1169/2011). Various options for the country of origin or the place of provenance are set out along with mandatory presentation (e.g. font size and field of vision). The regulation will apply from 1 April 2020.³⁶⁷

Commission Decision (EU) 2018/1304 of 19 September 2018 (document C(2018) 6054³⁶⁸) registered a proposed citizens' initiative entitled 'Eat ORIGINAL! Unmask your food'. This initiative calls on the European Commission 'to impose mandatory declaration of origin for all food products in order to prevent frauds, protect public health and guarantee consumers' right to information.' The objectives of the proposed citizens' initiative are: (1). Make the indication of the country of origin mandatory for all processed and unprocessed foods circulating in EU, with no derogation for registered trademarks and geographical indications. (2). With regard to processed foods, origin labelling is made mandatory for primary ingredients when different from the origin of the final product. (3). Improve consistency of labels including harmonized information about production and processing methods in order to ensure transparency throughout the food chain. The proposal is pursuant to Regulation (EU) No 211/2011³⁶⁹ which details the next steps which include gathering a minimum level of support for the proposal from Member States.

3.1.3 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).³⁷⁰

The Sea Fish (Marketing Standards) (England and Wales and Northern Ireland) Regulations 2018 were made by Defra in March 2018, coming into force on 30 April 2018. The Regulations enable the enforcement of EU common marketing standards for fishery products contained in Council Regulation (EC) No. 2406/96 laying down common marketing standards for certain fishery products, and Regulation (EU) No. 1379/2013 of the European Parliament and of the Council on the common organisation of the markets in fishery and aquaculture products. The former set out organoleptic freshness criteria and size criteria. The Sea Fish (Marketing Standards) Regulations 1986 and their amendments in 1989 and 1994 are revoked.³⁷¹

See also Section 5.15 for Regulation 2074/2005 which includes methods and limit values for total volatile basic nitrogen (TVB-N) (a measure of freshness) in fish.

The Sea Fishing (Illegal, Unreported and Unregulated Fishing) Order (Northern Ireland) 2018 in force from 1 June 2018 makes provision for the enforcement of Council Regulation [\(EC\) No. 1005/2008](#) and Commission Regulation [\(EC\) 1010/2009](#) establishing restrictions and obligations relating to illegal, unreported and unregulated fishing. There are controls on movement of consignments of fishery products while verifications are carried out (which can include a request for assistance from the flag state of the fishing vessel to ensure the accuracy of the information contained within, or the validity of, the catch certificate). Provisions also exist for the refusal of importation or permission to use transshipment facilities in circumstances where a landing or transshipment declaration has not been submitted in accordance with requirements. Catches in

³⁶⁷ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.131.01.0008.01.ENG&toc=OJ:L:2018:131:TOC

³⁶⁸ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.244.01.0107.01.ENG&toc=OJ:L:2018:244:TOC

³⁶⁹ <https://eur-lex.europa.eu/eli/reg/2011/211/2015-07-28>

³⁷⁰ http://ec.europa.eu/fisheries/documentation/publications/eu-new-fish-and-aquaculture-consumer-labels-pocket-guide_en.pdf

³⁷¹ <http://www.legislation.gov.uk/ukxi/2018/437/contents/made>

contravention may be seized for sale, disposal or destruction, fees charged and certain prohibited activities offences punishable summarily or on indictment.³⁷²

3.1.4 Direct sale to the consumer

See Section 3.1.6 for a case in the European Court on the meaning of sale *directly to the final consumer or user* in the context of Article 28(2) of Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling.

3.1.5 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).³⁷³

3.1.6 Organic food

A new principal EU measure was published on 14 June 2018 repealing Council Regulation (EC) No 834/2007 of 28 June 2007 and replacing it with Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products. The new regulation shall apply from 1 January 2021. Regulation (EC) No 834/2007 continues to apply for the purpose of completing the examination of pending applications from third countries, as provided for in Article 58 of Regulation 2018/848. References to the repealed Regulation shall be construed as references to Regulation 2018/848.

The recitals to Regulation 2018/848 note the dynamic evolution of the organic sector, and a review carried out by the Commission showed that the EU legal framework governing organic production should be improved to provide for rules that correspond to the high expectations of consumers and that guarantee sufficient clarity for those to whom they are addressed. Experience gained with the application of Regulation (EC) No 834/2007 showed the need to make clear to which products the Regulation applies. Primarily, it covers products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the Treaty on the Functioning of the European Union (TFEU). For reasons of clarity, such other products not listed in Annex I to the TFEU are listed in an Annex to the new Regulation. Regulation 2018/848 gives wide scope for the Commission to adopt implementing acts on organic production and labelling after appropriate consultations and to take into account new production methods, new materials or international commitments.

Products originating from hunting or fishing of wild animals should not be considered organic since their production process cannot be fully controlled. Products prepared by mass caterers on their premises are not subject to Regulation 2018/848 and are therefore not to be labelled or advertised with the organic production logo of the European Union. The risk of non-compliance with organic production rules is considered higher in agricultural holdings which include units that are not managed under those rules. Therefore, after an appropriate conversion period, all agricultural holdings in the EU which aim to become organic must be entirely managed in compliance with the requirements applicable to organic production. However, holdings including both units managed under organic production rules and units managed under non-organic production rules should be allowed under certain conditions, including in particular the condition

³⁷² <https://www.legislation.gov.uk/nisr/2018/106/contents/made>

³⁷³ <https://www.gov.uk/guidance/food-labelling-giving-food-information-to-consumers>

of clear and effective separation between organic, in-conversion and non-organic production units and between the products produced by those units. The practice of growing plants in demarcated beds will not be allowed subject to a transition period of 10 years. Provisions concerning the composition of processed organic food and feed are to be laid down. In particular, such food should be produced mainly from organic agricultural ingredients or from other ingredients falling within the scope of this Regulation that are organic, with the limited possibility of using certain non-organic agricultural ingredients specified in this Regulation. In addition, only certain products and substances authorised in accordance with this Regulation should be allowed for use in the production of processed organic food and feed.

Detailed rules for the implementation of Regulation 834/2007, and hence Regulation (EU) 2018/848 are given in Commission Regulation (EC) No 889/2008 of 5 September 2008 which is amended fairly regularly hence EUR-Lex should be consulted for the most up-to-date version.

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

All foods sold as organic must originate from growers, processors and importers who are registered with an approved certification body and subject to regular inspection. A Defra list of UK approved organic control bodies is available.³⁷⁴

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.³⁷⁵

Commission Implementing Regulation (EU) 2017/838 of 17 May 2017 amended Regulation (EC) No 889/2008 as regards feed for certain organic aquaculture animals. Under Regulation (EC) No 889/2008, the animals concerned are to be fed with feed naturally available in ponds and lakes but permits the use of organic feed of plant origin or seaweed where natural feed resources are not available in sufficient quantities and establishes maximum percentages of fishmeal and fish oil that can be included in the feed ration of siamese catfish and shrimps where naturally available feed is supplemented. Naturally occurring feed is limited or non-existent in the hatchery stage and the rules on feeding penaeid shrimps, in particular Tiger shrimp (*Penaeus monodon*) would lead to malnutrition and increased mortality if applied in the juvenile stages in a hatchery environment. The Regulation is amended accordingly.³⁷⁶

Commission Implementing Regulation (EU) 2017/1473 of 14 August 2017 amended Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 to remove 'Bolicert Ltd' from the list of control authorities and control bodies competent to carry out controls and issue certificates in third countries for the purpose of organic equivalence.³⁷⁷

³⁷⁴ <https://www.gov.uk/government/publications/organic-certification-list-of-uk-approved-organic-control-bodies>

³⁷⁵ 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

³⁷⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0838>

³⁷⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.210.01.0004.01.ENG&toc=OJ:L:2017:210:TOC

A Commission Decision of 16 August 2017 (2017/C 273/03) notes Decision 2009/427/EC establishing an expert group for technical advice on organic production and extends from three to four years the term of membership, which may be renewed for not more than three terms.³⁷⁸ Commission Decision 2017/C 287/03 of 30 August 2017³⁷⁹ lists the names of the members of the group.

Commission Implementing Regulation (EU) 2017/1862 of 16 October 2017³⁸⁰ amended Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 on imports of organic products from third countries by extending the period for control bodies and authorities to submit requests for recognition to 31 October 2018. Commission Implementing Regulation (EU) 2017/2329 of 14 December 2017 further amended and corrected Regulation 1235/2008 on the arrangements for imports of organic products from third countries including Costa Rica, Japan, New Zealand, the Republic of Korea, Albania, Turkey, Indonesia and others.³⁸¹

Commission Implementing Regulation (EU) 2017/2273 of 8 December 2017 amended Regulation (EC) No 889/2008 to extend the period during which non-organically reared pullets for egg production of not more than 18 weeks can be brought into an organic livestock unit. Also extended is the period during which a maximum of 5% of non-organic protein feed can be used for porcine and poultry species raised on organic farms. The extensions are to 31 December 2018 and arise owing to lack of sufficient availability of their organic equivalents.³⁸²

Article 28 of Regulation 834/2007 imposes conditions of notification to the competent authorities and submission to a control body on any operator who trades in organic products from a third country. However (Art. 28(2)) Member States may exempt operators who (with provisos) sell products *directly to the final consumer or user*. The meaning of the later phrase was tested before the European Court, Case C-289/16,³⁸³ which ruled that Article 28(2) must be interpreted as meaning that, in order for products to be regarded as being sold 'directly', within the meaning of that provision, to the final consumer or user, it is necessary for the sale to occur in the presence of both the operator or his sales personnel and the final consumer. The author of the present report wonders if this may have implications for the interpretation of 'prepacked for direct sale' in Regulation 1169/2011 (Food Information to Consumers)?

Council Decision (EU) 2017/2307 of 9 October 2017 noted the conclusion of an Agreement between the European Union and the Republic of Chile on trade in organic products to recognise the equivalence of their respective rules on organic production and control systems as regards organic products.³⁸⁴ The full text of the Agreement is available.³⁸⁵

The European Court (Fourth Chamber) set aside a judgement of the General Court of the European Union of 11 March 2016 (unpublished) and referred the case back to the General Court. This was an Appeal brought on 13 May 2016 by Binca Seafoods GmbH against the order of the General Court (Fourth Chamber) delivered on 11 March 2016 in Case T-94/15 Binca Seafoods GmbH v European Commission (Case C-268/16 P), (2016/C 279/22), language of the

³⁷⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.273.01.0003.01.ENG&toc=OJ:C:2017:273:TOC
³⁷⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.287.01.0003.01.ENG&toc=OJ:C:2017:287:TOC
³⁸⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.266.01.0001.01.ENG&toc=OJ:L:2017:266:TOC
³⁸¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.333.01.0029.01.ENG&toc=OJ:L:2017:333:TOC
³⁸² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.326.01.0042.01.ENG&toc=OJ:L:2017:326:TOC
³⁸³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.412.01.0010.01.ENG&toc=OJ:C:2017:412:TOC
³⁸⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.331.01.0001.01.ENG&toc=OJ:L:2017:331:TOC
³⁸⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.331.01.0004.01.ENG&toc=OJ:L:2017:331:TOC

case, German.³⁸⁶ Binca Seafoods claimed that the Court should annul the order of the Court of 11 March 2016 and annul Commission Implementing Regulation (EU) No 1358/2014 of 18 December 2014 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 as regards organic aquaculture. The appellant is a company registered under German law and enjoying organic certification. It imports into Germany 'pangasius', produced in Vietnam at a fish farm called Binca Organic Farm within the framework of organic aquaculture, which it then sells to commercial partners established in Germany, Austria and Scandinavia. Binca complained it was discriminated against as a provider of pangasius aquaculture products in Vietnam in relation to providers of aquaculture animal products, in particular those in the European Union, in relation to which transitional provisions were extended by the contested regulation beyond the end of 2015, whereas those provisions terminated in relation to pangasius. The appellant alleged that its competitors were able, as a result of arbitrary advantages, to offer their products with the 'Bio' label, whereas it was unable to benefit from that. It claimed that the competitors had an unfair and completely unjustified competitive advantage. The Appeal Judges took the view, *inter alia*, that the General Court erred in law by having wrongly held that the action brought before it by Binca sought the annulment of the regulation at issue solely on the ground that that regulation did not extend the transitional period, which resulted in the incorrect reclassification of the action. However, the Fourth Chamber Appeal Court did not have sufficient information to rule on the other arguments developed in the objection of inadmissibility raised by the Commission against Binca's action for annulment as well as on the substance of the case hence the referral back to the General Court, the judgement should be consulted for a fuller exposition of the arguments.³⁸⁷

Commission Implementing Regulation (EU) 2018/949³⁸⁸ of 3 July 2018 amended Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 on imports of organic products from third countries. The new implementing regulation makes a series of changes to control bodies notified by a range of third countries.

3.1.7 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.³⁸⁹

3.1.8 Protected names and quality schemes

There are three protection marks in the EU:³⁹⁰

- 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.³⁹¹

³⁸⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.072.01.0011.02.ENG&toc=OJ:C:2018:072:TOC

³⁸⁷ <http://curia.europa.eu/juris/document/document>

³⁸⁸ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.167.01.0003.01.ENG&toc=OJ:L:2018:167:TOC

³⁸⁹ 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>

³⁹⁰ http://ec.europa.eu/agriculture/quality/schemes/index_en.htm

Council Decision (EU) 2017/1912 of 9 October 2017³⁹² established Agreement³⁹³ between the EU and Iceland on the protection of geographical indications for agricultural products and foodstuffs.

Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 sets out the rules on quality schemes for agricultural products and foodstuffs, including PGI, PDO and TSG.³⁹⁴

Council Decision (EU) 2018/416 of 5 March 2018³⁹⁵ authorised the opening of negotiations for a revised Lisbon Agreement on Appellations of Origin and Geographical Indications. The Lisbon Agreement for the Protection of Appellations of Origin and their International Registration of 1958 is a treaty administered by the World Intellectual Property Organization (WIPO). It is open to parties to the Paris Convention for the Protection of Industrial Property. It has a membership of 28 contracting parties, including seven Union Member States (Bulgaria, Czech Republic, France, Italy, Hungary, Portugal and Slovakia). A useful presentation on Geographical Indications and Appellations of Origin is available from the WIPO.³⁹⁶

3.1.8.1 Champagne sorbet case

This is a case before the European Court concerning the use of the protected designation of origin (PDO) ‘Champagne’ in the name of a frozen product ‘Champagner Sorbet’ distributed by Aldi since 2012, and containing, among its ingredients, 12% champagne. The text of the judgement³⁹⁷ of the Court (Second Chamber) of 20 December 2017 should be read³⁹⁸ for a full exposition of the law and the questions asked of the Court. In essence the operative part of the judgment³⁹⁹ is as follows.

- a) The applicable law (the then Regulation 1234/2007 establishing a common organisation of agricultural markets ... the ‘Single CMO Regulation’ as amended [see Judgement for details] and Regulation No 1308/2013, which replaced it with effect from 1 January 2014) is to be interpreted as meaning that the scope of those provisions covers a situation where a protected designation of origin, PDO, such as ‘Champagne’, is used as part of the name under which a foodstuff is sold, such as ‘Champagner Sorbet’, and where that foodstuff does not correspond to the product specifications for that protected designation of origin but contains an ingredient which does correspond to those specifications.
- b) The use of a PDO as part of the name such as ‘Champagner Sorbet’ under the above conditions constitutes exploitation of the reputation of a PDO, if that foodstuff does not have, as one of its essential characteristics, a taste attributable primarily to the presence of that ingredient in the composition of the foodstuff.
- c) The use of a PDO as part of the name under which is sold a foodstuff that does not correspond to the product specifications for that PDO but contains an ingredient that does correspond to those specifications, such as ‘Champagner Sorbet’, does not constitute misuse, imitation or evocation within the meaning of the referred provisions.

³⁹¹ <https://www.gov.uk/guidance/eu-protected-food-names-how-to-register-food-or-drink-products>

³⁹² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.274.01.0001.01.ENG&toc=OJ:L:2017:274:TOC

³⁹³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.274.01.0003.01.ENG&toc=OJ:L:2017:274:TOC

³⁹⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1488746464115&uri=CELEX:02012R1151-20130103>

³⁹⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.075.01.0023.01.ENG&toc=OJ:L:2018:075:TOC

³⁹⁶ http://www.fao.org/fileadmin/templates/est/COMM_MARKETS_MONITORING/Tea/Documents/Wipo_FAO-IGGtea-GI-AO-mg-10-05-13.pdf

³⁹⁷ Request for a preliminary ruling from the Bundesgerichtshof — Germany) — Comité Interprofessionnel du Vin de Champagne v Aldi Süd Dienstleistungs-GmbH & Co. OHG, represented by Aldi Süd Dienstleistungs-GmbH, formerly Aldi Einkauf GmbH & Co. OHG Süd (Case C-393/16).

³⁹⁸ <http://curia.europa.eu/juris/document/document.jsf?docid=198044&doclang=EN>

³⁹⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.072.01.0017.01.ENG&toc=OJ:C:2018:072:TOC

- d) The referred provisions are to be interpreted as being applicable both to false or misleading indications which are liable to convey a false impression as to the geographical origin of the product concerned and to false or misleading indications relating to the nature or essential qualities of the product.

These proceedings are a step in the action pending before the national court, the Bundesgerichtshof (Federal Court of Justice, Germany) and it will be interesting to see how the matter is finally settled.

3.2 Dual quality products

In September 2017 the Commission issued a notice (2017/C 327/01)⁴⁰⁰ on the application of EU food and consumer protection law to the dual quality of food products. The notice stated that free movement of goods is one of the four fundamental freedoms of the Single Market but does not necessarily mean that every product must be identical in every corner of the Single Market. Whilst consumers are free to buy the products of their choice, business operators are also free to market and sell goods with different composition or characteristics, provided that they fully respect EU legislation (whether on the safety of products, labelling or other horizontal or sectoral legislation). However, a source of concern can be when the different composition of identically branded goods has the potential to mislead the consumer.

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

The current notice lists the relevant legislation, general food law, (Regulation 178/2002), the food information to consumers' regulation (Regulation 1169/2011) and the unfair commercial practices directive (Directive 2005/29/EC) as well as product specific law such as on chocolate, jam and fruit juice. The notice discusses the interaction between such measures and gives advice on their application, including cross border cooperation and a flow chart to help assess unfair business practices in the case of branded food products.

3.3 Composition

3.3.1 Casein and caseinates

Directive (EU) 2015/2203 of the European Parliament and of the Council of 25 November 2015 brought up to date the approximation of the laws of the Member States relating to caseins and caseinates intended for human consumption and repeals Council Directive 83/417/EEC.⁴⁰¹ 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

⁴⁰⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.327.01.0001.01.ENG&toc=OJ:C:2017:327:TOC
⁴⁰¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1481228098768&uri=CELEX:32015L2203>

('Codex standard for edible casein products').⁴⁰² Domestic implementation was formalised in late 2016 by the Caseins and Caseinates (Wales) Regulations 2016 No.1130 (W.270)⁴⁰³ and the Caseins and Caseinates Regulations (Northern Ireland) 2016 No.415.⁴⁰⁴ The Caseins and Caseinates (Scotland) Regulations 2016 No.383⁴⁰⁵ were made but were replaced on 15 December 2016 by the Caseins and Caseinates (Scotland) (No. 2) Regulations 2016⁴⁰⁶ owing to defects in S.S.I. 2016/383.

Domestic implementation of Directive (EU) 2015/2203 was completed in July 2017 in England by the Caseins and Caseinates (England) Regulations 2017 which came into force on 26 September 2017.⁴⁰⁷

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

3.3.2 Condensed milk and dried milk

In March 2018 the Condensed Milk and Dried Milk (Wales) Regulations 2018⁴⁰⁸ were made, coming into force on 26 March 2018. The regulations transpose into Welsh law Council Directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption. The regulations define condensed milk and dried milk products and the reserved descriptions that apply to them, prohibit the labelling with reserved descriptions of food other than the designated condensed and dried milk products to which they relate, set out labelling requirements and apply certain provisions of the Food Safety Act 1990 (1990 c. 16) with modifications. This includes the application of section 10(1) (with modifications) and (2), enabling an improvement notice to be served to require compliance with the regulations. The provisions, as applied, make the failure to comply with an improvement notice an offence under section 10(2). The Condensed Milk and Dried Milk (Wales) Regulations 2003, the Condensed Milk and Dried Milk (Wales) (Amendment) Regulations 2008 and Regulation 33(2) of the Food Hygiene (Wales) Regulations 2006 are revoked.

The Condensed Milk and Dried Milk Regulations (Northern Ireland) 2018 were also made in March 2018, and came into force on 23 April 2018 and similarly transpose Directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption. They revoke and replace the Condensed Milk and Dried Milk Regulations (Northern Ireland) 2003 (SR 2003 No.300) and revoke the Condensed Milk and Dried Milk (Amendment) Regulations (Northern Ireland) 2008 (SR 2008 No.42) and Schedule 7 paragraphs 18 and 19 of the Food Hygiene Regulations (Northern Ireland) 2006 (SR 2006 No.3). They apply certain provisions of the Food Safety (Northern Ireland) Order 1991 as amended) with modifications. This includes the application of Article 9(1) (with modifications) and (2), enabling an improvement notice to be served to require compliance with regulations 3, 4 or 5. The provisions, as applied, make the failure to comply with an improvement notice an offence.⁴⁰⁹

⁴⁰² 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%252FBSTAN%252B290-1995%252FCXS_290e.pdf

⁴⁰³ <http://legislation.data.gov.uk/wsi/2016/1130/contents/made/data.htm?wrap=true>

⁴⁰⁴ <http://www.legislation.gov.uk/nisr/2016/415/contents/made>

⁴⁰⁵ http://www.legislation.gov.uk/ssi/2016/383/pdfs/ssi_20160383_en.pdf

⁴⁰⁶ http://www.legislation.gov.uk/ssi/2016/422/pdfs/ssi_20160422_en.pdf

⁴⁰⁷ <http://www.legislation.gov.uk/uksi/2017/848/note/made>

⁴⁰⁸ <http://www.legislation.gov.uk/wsi/2018/275/contents/made>

⁴⁰⁹ <http://www.legislation.gov.uk/nisr/2018/77/contents/made>

3.3.3 Infants, young children, special medical purposes or total diet replacement for weight control

Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 covers food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplements Regulation 609/2013 by laying down, *inter alia*, compositional and labelling rules for infant formula and follow-on formula. Commission Delegated Regulation (EU) 2018/561 of 29 January 2018 amended Delegated Regulation 2016/127 to reduce the minimum protein content required under the delegated regulation for follow-on formula based on cow's milk or goat's milk protein to 1.6 g/100 kcal (0.38 g/100kJ). This arose from a request from a food business operator for the placing on the market of a follow-on formula based on intact protein from cow's milk with a protein content of at least 1.61 g/100 kcal. EFSA considered this safe and suitable for healthy infants living in Europe with an intake of complementary foods of a sufficient quality and if the product otherwise complies with the requirements of the relevant EU rules. On the basis of that opinion, and in order to foster the development of innovative products, the change was made.⁴¹⁰

3.3.4 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 1962.⁴¹¹

3.3.5 Honey

The making and coming into force of the Honey (Wales) Regulations 2015⁴¹² (SI 1507, W174) completed the updating of domestic implementation of Council Directive 2001/110/EC relating to honey.⁴¹³ These regulations sit alongside the Honey (Scotland) Regulations 2015 (SSI 208),⁴¹⁴ the Honey Regulations (Northern Ireland) 2015 (SR 261),⁴¹⁵ and the Honey Regulations (England) 2015⁴¹⁶ (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

⁴¹⁰ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_2018.094.01.0001.01.ENG&toc=OJ:L:2018:094:TOC

⁴¹¹ http://www.oecd-ilibrary.org/agriculture-and-food/international-standards-for-fruit-and-vegetables_19935668

⁴¹² http://www.legislation.gov.uk/wsi/2015/1507/pdfs/wsi_20151507_mi.pdf

⁴¹³ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1445979649018&uri=CELEX:02001L0110-20140623>

⁴¹⁴ <http://www.legislation.gov.uk/ssi/2015/208/contents/made>

⁴¹⁵ <http://www.legislation.gov.uk/nisr/2015/261/contents/made>

⁴¹⁶ http://www.legislation.gov.uk/ukxi/2015/1348/pdfs/ukxi_20151348_en.pdf

from being served in relation to such food if it would have been compliant with the 2003 Honey Regulations.

A coordinated control plan to assess the prevalence on the market of honey adulterated with sugars and honeys mislabelled with regard to their botanical source or geographical origin is described on the Commission website.⁴¹⁷ The non-compliances detected by the Member States were mostly related to the declaration of the botanical source (7%) and to adulteration with sugar (6%). Non-compliances related to the declaration of the geographical origin were less frequent (2%). Some non-compliances related to the botanical source are probably unintentional and the result of bees foraging a wide variety of plants, despite the hives being very close to the plant species identified as the botanical source. Member States also submitted to the Commission Joint Research Centre, JRC,⁴¹⁸ 893 samples of honey which they had found to be compliant or suspicious. The JRC applied liquid chromatography-isotope ratio mass spectrometry, which can better distinguish different sugars than current validated methods. The findings⁴¹⁹ were that 14% of the samples they tested contained added sugar. This was further broken down according to geographical origin, point of collection (i.e. producer, packager or retailer) and type of honey. Overall, the results from the honey coordinated control plan indicate that the practice of adding sugars to honey is occurring, both within the EU and in third countries. The Commission will discuss with the relevant stakeholders an appropriate follow-up to this control plan.

The New Zealand Ministry for Primary Industries has published scientific definition for New Zealand mānuka honey.⁴²⁰

See also D. Thorburn Burns, Anne Dillon, John Warren, and Michael J. Walker, 2018, A Critical Review of the Factors Available for the Identification and Determination of Mānuka Honey, *Food Analytical Methods*, 11, 1561-1167 (open access).⁴²¹

3.3.6 Jam and similar products

The Jam and Similar Products (Wales) Regulations 2018⁴²² were made on 27 February 2018 and came into force on 26 March 2018. They provide for the continuing implementation of Council Directive 2001/113/EC relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption. They also retain existing national measures relating to curds, lemon cheese and [sweet] mincemeat. The Regulations revoke and replace the Jam and Similar Products (Wales) Regulations 2004. Use of names such as “jam”, “extra jam”, “jelly”, “extra jelly”, “marmalade”, “jelly marmalade”, “sweetened chestnut purée”, “curd”, “lemon cheese” and “mincemeat” remain permitted subject to prescribed compositional criteria. Labelling requirements including fruit and sugar content, and on residual sulphur dioxide continue. The Regulations introduce relevant provisions of the Food Safety Act 1990 enabling an improvement notice to be served to require compliance, making the failure to comply with an improvement notice an offence.

The Jam and Similar Products Regulations (Northern Ireland) 2018, which came into operation on 23 April 2018 make similar provisions and revoke the Jam and Similar Products Regulations (Northern Ireland) 2003. The regulations apply certain provisions of the Food Safety (Northern

⁴¹⁷ https://ec.europa.eu/food/safety/official_controls/food_fraud/honey_en

⁴¹⁸ <https://ec.europa.eu/jrc/en>

⁴¹⁹ https://ec.europa.eu/food/sites/food/files/safety/docs/oc_control-progs_honey_jrc-tech-report_2016.pdf

⁴²⁰ <https://www.mpi.govt.nz/growing-and-producing/bees-and-other-insects/manuka-honey/>

⁴²¹ <https://link.springer.com/article/10.1007%2Fs12161-018-1154-9>

⁴²² http://www.legislation.gov.uk/wsi/2018/274/pdfs/wsi_20180274_mi.pdf

Ireland) Order 1991 as amended). This includes the application of Article 9, enabling an improvement notice to be served to require compliance with specified provisions of these Regulations. The provisions, as applied, make the failure to comply with an improvement notice an offence (regulation 10 and Schedule 4).⁴²³

3.3.7 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.⁴²⁴ 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 2013⁴²⁵ 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 2016⁴²⁶ amending minor drafting errors in the 2013 regulations.

Regulation (EU) 2017/2393 of the European Parliament and of the Council of 13 December 2017 amended a number of Regulations mainly concerning the common agricultural policy, but also 1308/2013. Annex III of Regulation (EU) 2017/2393 amended Annexes VII and VIII to Regulation 1308/2013 in relation to its Annex VII, on the upper limit for the total alcoholic strength which may now exceed 15% volume for wines with a protected designation of origin which have been produced as detailed in the amendment. The measure also made minor changes in Annex VIII for years when climatic conditions have been exceptionally unfavourable for wine.⁴²⁷

The European Court (Seventh Chamber) on 14 June 2017 gave a preliminary ruling with regard to the sales descriptions 'milk' and 'milk products'. The case was referred from a German court where the Applicant was Verband Sozialer Wettbewerb eV, a German association safeguarding competition, and the Defendant was TofuTown.com GmbH. The ECJ held that Regulation 1308/2013 (Article 78(2) and Annex VII, Part III) must be interpreted as precluding the term 'milk' and the designations reserved by that regulation exclusively for milk products from being used to designate a purely plant based product in marketing or advertising, even if those terms are expanded upon by clarifying or descriptive terms indicating the plant origin of the product at issue, unless that product is listed in Annex I to Commission Decision 2010/791/EU of 20 December 2010 listing the products referred to in the second subparagraph of point III(1) of Annex XII to Council Regulation (EC) No 1234/2007.⁴²⁸

Commission Implementing Regulation (EU) 2018/1146 of 7 June 2018⁴²⁹ amended Implementing Regulation (EU) 2017/892 laying down rules for the application of Regulation (EU) No 1308/2013 with regard to the fruit and vegetables and processed fruit and vegetables sectors (national

⁴²³ <http://www.legislation.gov.uk/nisr/2018/78/regulation/1/made>

⁴²⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32013R1308>

⁴²⁵ http://www.legislation.gov.uk/ukxi/2013/3235/pdfs/ukxi_20133235_en.pdf

⁴²⁶ <http://www.legislation.gov.uk/ukxi/2013/3235/made>

⁴²⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.350.01.0015.01.ENG&toc=OJ:L:2017:350:TOC

⁴²⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.277.01.0018.01.ENG&toc=OJ:C:2017:277:TOC

⁴²⁹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.208.01.0009.01.ENG&toc=OJ:L:2018:208:TOC#ntr1-L_2018208EN.01000901-E0001

financial assistance) and Regulation (EC) No 606/2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices (e.g. increase in the natural alcoholic strength by volume) and the applicable restrictions.

See also Section 3.1.8.1 for the case 'Champagne Sorbet'.

3.3.8 Milk and milk products – intervention and analysis

Commission Delegated Regulation (EU) 2018/149 of 15 November 2017 amended Delegated Regulation (EU) 2016/1238 with regard to the compositional requirements and quality characteristics of milk and milk products eligible for public intervention and aid for private storage. This was occasioned by technical improvements in the methods used in the analysis and quality evaluation of milk and milk products and in order to align existing EU rules relating to hygiene requirements, and updated the parameters of the compositional requirements and quality characteristics of certain milk products eligible for public intervention and aid for private storage.⁴³⁰ Commission Implementing Regulation (EU) 2018/150 of 30 January 2018 amended Implementing Regulation (EU) 2016/1240 on methods for the analysis and quality evaluation of milk and milk products eligible for intervention and aid with updated references to ISO standards and certain statutory methods. The latter included the quantitative determination of phosphatidylserine and phosphatidylethanolamine in skimmed milk powder, as o-phthalaldehyde derivatives by reversed-phase LC with fluorescence detection, detection of rennet whey in skimmed milk powder by the LC determination of caseinomacropptides, and detection of cow's milk and caseinate in cheeses from ewe's milk, goat's milk or buffalo milk or their mixtures by isolation of caseins, plasmin cleavage and isoelectric focusing.⁴³¹

3.3.9 Free range eggs

Commission Regulation (EC) No 589/2008 (2) lays down detailed rules for implementing Council Regulation (EC) No 1234/2007 (which was repealed and replaced by Regulation (EU) No 1308/2013) as regards marketing standards for eggs. Commission Delegated Regulation (EU) 2017/2168 of 20 September 2017⁴³² amended Regulation (EC) No 589/2008 as regards marketing standards for free range eggs where hens' access to open air runs is restricted.

3.3.10 Meat and meat products

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

The Products Containing Meat etc. Regulations 2014 enacted in England (e.g. SI 3001/2014⁴³³), 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).⁴³⁴

⁴³⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.026.01.0011.01.ENG&toc=OJ:L:2018:026:TOC

⁴³¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.026.01.0014.01.ENG&toc=OJ:L:2018:026:TOC

⁴³² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.306.01.0006.01.ENG&toc=OJ:L:2017:306:TOC

⁴³³ http://www.legislation.gov.uk/ukxi/2014/3001/pdfs/ukxi_20143001_en.pdf

⁴³⁴ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review>

Similar Regulations have been enacted in Scotland with the Products Containing Meat etc. Regulations (Scotland) Regulations 2014 (SSI 289/2014)⁴³⁵ 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) 2014⁴³⁶ (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).⁴³⁷

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

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

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

⁴³⁵ http://www.legislation.gov.uk/ssi/2014/289/pdfs/ssi_20140289_en.pdf

⁴³⁶ http://www.legislation.gov.uk/nisr/2014/285/pdfs/nisr_20140285_en.pdf

⁴³⁷ http://www.legislation.gov.uk/ssi/2016/24/pdfs/ssi_20160024_en.pdf

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

The interested reader is advised to consider the full judgements:

Judgment of the Court (Tenth Chamber) 16 October 2014, Case C-453/13, Request for a preliminary ruling under Article 267 TFEU from the High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court) (United Kingdom), in the proceedings The Queen, on the application of: Newby Foods Ltd v Food Standards Agency,⁴³⁸ and Case No: C1/2016/2112, In the Court of Appeal (Civil Division) on Appeal From High Court, Queen's Bench Division, Administrative Court, Mr. Justice Edwards-Stuart, CO69232012, (Jones, LJ, Beatson LJ and Moyland LJ).⁴³⁹

See also Section 2.12 in relation to mechanically recovered meat and TSE, and Section 2.13.1 on the carcinogenicity of red meat and processed meat.

3.3.11 Olive oil and table olives

Pursuant to Article 91 of Regulation (EU) No 1308/2013 on the common organisation of the markets in agricultural products, Commission Regulation (EEC) No 2568/91 defines the chemical and organoleptic characteristics of olive and olive-pomace oil, and lays down methods of assessing those characteristics. Regulation (EEC) No 2568/91 methods are regularly updated in line with the work of the International Olive Council. The Olive Oil (Marketing Standards) Regulations 2014, which apply to the whole of the UK, and for which a correction slip has been issued (September 2016) implement the above.⁴⁴⁰ 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 2016.⁴⁴¹ Guidance on olive oil composition, characteristics and labelling is available from Defra.⁴⁴²

A corrigendum was issued on 26 September 2016 to Commission Delegated Regulation (EU) 2016/2095 amending Regulation (EEC) No 2568/91 on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis. Certain limits for purity characteristics were corrected.⁴⁴³

Commission Delegated Regulation (EU) 2018/1096⁴⁴⁴ of 22 May 2018 amended Implementing Regulation (EU) No 29/2012 as regards the requirements for certain indications on the labelling of olive oil. These indications included labelling of the acidity but only if peroxide value, waxes content and ultraviolet absorption are also indicated and values are the maximum expected by the date of minimum durability. Indication of the year of harvest is also permitted subject to certain rules.

3.3.12 Spices

The British Retail Consortium (BRC), Food and Drink Federation (FDF) and Seasoning and Spice Association (SSA) in liaison with the FSA and FSS have issued guidance for food companies that

⁴³⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1505653462283&uri=CELEX:62013CJ0453>

⁴³⁹ <http://www.bailii.org/ew/cases/EWCA/Civ/2017/400.html>

⁴⁴⁰ <http://origin-www.legislation.gov.uk/ukxi/2014/195/contents/made>

⁴⁴¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1080>

⁴⁴² <https://www.gov.uk/guidance/olive-oil-regulations-and-inspections>

⁴⁴³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.211.01.0058.01.ENG&toc=OJ:L:2017:211:TOC

⁴⁴⁴ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.197.01.0003.01.ENG&toc=OJ:L:2018:197:TOC

use culinary dried herbs and spices with information on best practice in assessing and protecting the authenticity of these products.^{445, 446}

3.3.13 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.⁴⁴⁷ Commission Regulation (EC) No 2870/2000⁴⁴⁸ lists and describes the reference methods for the analysis of spirit drinks.

The Commission aims better to align the existing Regulation (EC) No 110/2008 on spirit drinks with the Treaty on the Functioning of the European Union. In June 2017 the European Economic and Social Committee published⁴⁴⁹ a generally supportive opinion on the proposal. On presentation and labelling, the Committee suggested avoiding any kind of misrepresentation or misunderstanding in relation to 'imitation flavours'; Article 8(5) of the Commission proposal specifies that the sales denominations supplemented by the term 'flavour' (or any other similar terms) may be used to refer to flavourings that imitate a spirit drink or their use in the production of a foodstuff other than a beverage. The Committee considered that this provision could be misleading for consumers. The Committee also requested strengthened arrangements to allow fake spirits to be removed from the market.

Commission Regulation (EU) 2018/1098⁴⁵⁰ of 2 August 2018 amended and correcting Annex III to Regulation (EC) No 110/2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks. The amendments generally concern non UK spirit drinks however the entry 'Ireland' related to 'Irish Poteen/Irish Poitín' is clarified to cover the corresponding spirit drink produced in [the Republic of] Ireland and Northern Ireland.

The Court of Justice of the European Union gave a preliminary ruling on the interpretation of Regulation (EC) No 110/2008 on spirit drinks⁴⁵¹ in relation to the registered geographical indication 'Scotch Whisky'. The request had been made in proceedings between the Scotch Whisky Association and Mr Michael Klotz, an online distributor of whisky, seeking an order that Mr Klotz cease to market a whisky produced in Germany under the designation 'Glen Buchenbach' before the Landgericht Hamburg (Regional Court, Hamburg). The label on the whisky bottles in question includes, in addition to a stylised depiction of a hunting horn (*Waldhorn* in German), the following information: '*Waldhornbrennerei*' (Waldhorn distillery), 'Glen Buchenbach', 'Swabian Single Malt Whisky', '500 ml', '40% vol', '*Deutsches Erzeugnis*' (German product), '*Hergestellt in den Berglen*' (produced in the Berglen). The Hamburg court took the view that whether the claim is to succeed depends on the interpretation to be given to Article 16(a) to (c) of Regulation No 110/2008 and stayed the proceedings pending referral of a set of questions to the Court of Justice.⁴⁵² The Court decided that:

1. Article 16(a) of Regulation (EC) No 110/2008 must be interpreted as meaning that, for the purpose of establishing that there is 'indirect commercial use' of a registered geographical indication, the disputed element must be used in a form that is either identical to that indication or phonetically and/or visually similar to it. *Accordingly, it is not sufficient that*

⁴⁴⁵ <https://www.fdf.org.uk/news.aspx?article=7539>

⁴⁴⁶ <https://www.fdf.org.uk/herbs-spices-guidance.aspx>

⁴⁴⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474277348569&uri=CELEX:02008R0110-20160705>

⁴⁴⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1499102421377&uri=CELEX:02000R2870-20160426>

⁴⁴⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.209.01.0054.01.ENG&toc=OJ:C:2017:209:TOC

⁴⁵⁰ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.197.01.0007.01.ENG&toc=OJ:L:2018:197:TOC

⁴⁵¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.268.01.0010.01.ENG&toc=OJ:C:2018:268:TOC

⁴⁵² <https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX%3A62017CJ0044>

that element is liable to evoke in the relevant public some kind of association with the indication concerned or the geographical area relating thereto.

2. Article 16(b) of Regulation No 110/2008 must be interpreted as meaning that, for the purpose of establishing that there is an 'evocation' of a registered geographical indication, the referring court is required to determine whether, when the average European consumer who is reasonably well informed and reasonably observant and circumspect is confronted with the disputed designation, the image triggered directly in his mind is that of the product whose geographical indication is protected. In making that determination, the referring court, in the absence of (i) any phonetic and/or visual similarity between the disputed designation and the protected geographical indication and (ii) any partial incorporation of that indication in that designation, must take account of the conceptual proximity, if any, between the designation and the indication. Article 16(b) of Regulation No 110/2008 must be interpreted as meaning that, for the purpose of establishing that there is an 'evocation' of a registered geographical indication, account is not to be taken either of the context surrounding the disputed element, or, in particular, of the fact that that element is accompanied by an indication of the true origin of the product concerned.
3. Article 16(c) of Regulation No 110/2008 must be interpreted as meaning that, for the purpose of establishing that there is a 'false or misleading indication', as prohibited by that provision, account is not to be taken of the context in which the disputed element is used.

The Court of Justice notes that its proceedings are, for the parties to the main proceedings, a step in the action pending before the national court. It will be of interest to see how the German court finally disposes of the matter however in the opinion of this writer the higher court's directions appear to tip the scales against the applicant.

3.3.13.1 Analytical tolerances – fruit-based liqueur declarations

An opinion was published in December 2017 by the Government Chemist following a disagreement between a producer of fruit based liqueurs and the public analyst about the correct tolerance to apply to their declared alcohol content. Alcoholic drinks above a certain strength must bear a declaration of their alcoholic strength. The declaration must be accurate within certain tolerances. Two options are available, either:

- a) a tolerance of 1.5% (absolute) which applies to alcoholic drinks containing macerated fruit or parts of plants, or
- b) a tolerance of 0.3% (absolute) which applies to other beverages containing more than 1.2% by volume of alcohol.

For the reasons given in the opinion, it is considered that a tolerance of 0.3% vol. absolute is appropriate for a filtered liqueur.⁴⁵³

Commission Regulation (EU) 2018/175 of 2 February 2018 amended Annex II to Regulation 110/2008. This Annex provides that the sales denomination of spirit drinks of the category 9 'Fruit spirit' has to be 'spirit' preceded by the name of the fruit, berry or vegetable used. However, in some official languages those sale denominations are traditionally expressed by completing the name of the fruit with a suffix. The indication of a sale denomination consisting of the name of the fruit completed by a suffix is therefore allowed for fruit spirits labelled in those official languages. The specifications of the category 10 'Cider spirit and perry spirit' do not clearly provide for the possibility of distilling cider and perry together in order to produce this category of spirit drink and this has been corrected.⁴⁵⁴

⁴⁵³ <https://www.gov.uk/government/publications/published-opinion-on-analytical-tolerances-for-alcohol-declarations>
⁴⁵⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.032.01.0048.01.ENG&toc=OJ:L:2018:032:TOC

3.3.14 Wine

Wine law is complex and extensive; a readable guide is on the FSA website with links to European legislation.⁴⁵⁵ Regulation 1308/2013 on the common organisation of the markets in agricultural products also applies, (see Section 3.3.7). There is no ready compendium of EU legislation on wine.

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

Recent updates include Commission Delegated Regulation (EU) 2017/670⁴⁵⁶ of 31 January 2017, published in April 2017, supplementing Regulation (EU) No 251/2014⁴⁵⁷ on authorised production processes for aromatised wine products, which includes, for example, vermouth and sangria. Regulation 2017/670 updates the production processes recommended and published by the International Organisation of Vine and Wine (OIV),⁴⁵⁸ which provides much useful information including methods of analysis.

Commission Delegated Regulation (EU) 2017/1353 of 19 May 2017 amended Regulation (EC) No 607/2009 as regards the wine grape varieties and their synonyms that may appear on wine labels. The regulation seeks to resolve a dispute between Croatia and Slovenia on use of the wine grape variety name 'Teran'.⁴⁵⁹

Commission Implementing Regulation (EU) 2017/2281 of 11 December 2017 authorised an increase of the limits for the enrichment of wine produced using the grapes harvested in 2017 in certain wine-growing regions of Germany and in all wine-growing regions of Denmark, the Netherlands and Sweden owing to exceptionally unfavourable climatic conditions.⁴⁶⁰

Commission Delegated Regulation (EU) 2018/273 of 11 December 2017 supplemented Regulation (EU) No 1308/2013 on the scheme of authorisations for vine plantings, the vineyard register, accompanying documents and certification, the inward and outward register, compulsory declarations, notifications and publication of notified information, and supplementing Regulation (EU) No 1306/2013 of the European Parliament and of the Council as regards the relevant checks and penalties, amending Commission Regulations (EC) No 555/2008, (EC) No 606/2009 and (EC) No 607/2009 and repealing Commission Regulation (EC) No 436/2009 and Commission Delegated Regulation (EU) 2015/560. Analytical requirements and tolerances are given for actual alcoholic strength, the refractive index of grape must, density expressed in grams per cm³, and the sugar content of concentrated grape must, rectified concentrated grape must and concentrated grape juice, expressed by the content in grams, per litre and per kilogram, of total sugars.

Commission Implementing Regulation (EU) 2018/274 of 11 December 2017 laid down rules for the application of Regulation (EU) No 1308/2013 on authorisations for vine plantings, certification, compulsory declarations and other administrative details, rules for Regulation (EU) No 1306/2013 on relevant checks, and repealed Commission Implementing Regulation (EU) 2015/561. Certification of wine products without a PDO or PGI is dealt with in Article 12 by administrative evidence to support the veracity of the wine grape variety(-ies) or the vintage year shown on the

⁴⁵⁵ <https://www.food.gov.uk/business-industry/winestandards/lawguide>

⁴⁵⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.097.01.0005.01.ENG&toc=OJ:L:2017:097:TOC

⁴⁵⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498062395786&uri=CELEX:02014R0251-20140327>

⁴⁵⁸ <http://www.oiv.int/>

⁴⁵⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.190.01.0005.01.ENG&toc=OJ:L:2017:190:TOC

⁴⁶⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.328.01.0017.01.ENG&toc=OJ:L:2017:328:TOC

label or conveyed in the presentation of the wines concerned. Member States may decide on an organoleptic test of the wine or an analytical test in case of a wine made from a single wine grape variety.⁴⁶¹

Commission Implementing Decision 2018/C 100/09 of 14 March 2018⁴⁶² published for a two month consultation an application for amendment of the specification for Chianti Classico (PDO), a name in the wine sector referred to in Article 105 of Regulation (EU) No 1308/2013. The amendment aims to provide greater assurance of the quality of the product. Analytical characteristics such as acidity and alcoholic strength are given. Similarly Commission Implementing Decision 2018/C 100/10 of 14 March 2018⁴⁶³ published for a two month consultation on the product specification for the protection of 'Ambt Delden' wine (PDO) from the Netherlands.

3.3.15 Water in frozen poultry

As with all animal species, poultry contains naturally present water, known as the 'physiological water'. Commercial processing in accordance with good manufacturing practice adds an amount of technically unavoidable water known as 'extraneous water'. European legislation⁴⁶⁴ sets limits for 'extraneous water' so that consumers are not being disadvantaged by excess 'extraneous water' in poultry meat they purchase.

A study funded by the European Commission and undertaken by LGC⁴⁶⁵ has provided a comprehensive account of the current technologies used in the processing of poultry in the EU and the amount of technologically unavoidable water added to broiler chickens by different chilling methods.

The results obtained showed that the largest observed effect on the water/protein ratio was for portion type, with 'breast' behaving very differently to 'leg' and 'carcase'. Chilling method did not have a significant effect on 'breast' and provides evidence for retention of a single legal limit for breast fillet. Immersion chilling adds significantly more water to 'leg' and 'carcase' than any other chilling method. This provides evidence for retention of a separate legal limit for immersion chilled carcasses but there is no strong evidence to require different limits for the other four chilling methods. 'Leg' also behaved very similarly to 'carcase' in this study. Thus it would be prudent to retain a separate legal limit for immersion chilled leg. Although this study has provided valuable information, data sets for some of the variables studied were small owing to the unavailability of some of the required samples, hence the results from this study should be treated with caution in considering future legislative limits.⁴⁶⁶

An interesting court case on water in poultry came before the (European) Court of Justice (Forth Chamber) with judgement given on 9 March 2017. This was a request for a preliminary ruling from a French court on Regulation (EC) No 543/2008 – Article 15(1) – Article 16 – Frozen or

⁴⁶¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.058.01.0060.01.ENG&toc=OJ:L:2018:058:TOC

⁴⁶² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.100.01.0007.01.ENG&toc=OJ:C:2018:100:TOC

⁴⁶³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.100.01.0014.01.ENG&toc=OJ:C:2018:100:TOC

⁴⁶⁴ Regulation (EU) No 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1501780319097&uri=CELEX:02013R1308-20170801> and Commission Regulation (EC) No 543/2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultrymeat: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R0543>.

⁴⁶⁵ <http://www.lgcgroup.com/about-us/media-room/latest-news/2017/lgc-completes-study-to-establish-uptake-of-water-d/#.WUzKHbpFxmU>

⁴⁶⁶ https://ec.europa.eu/agriculture/sites/agriculture/files/external-studies/2016-water-in-poultrymeat/final-report_en.pdf

quick-frozen chickens – Maximum limit for water content. The questions for the court were as follows:⁴⁶⁷

1. Does compliance with the water-content threshold laid down by Article 15 of Regulation (EC) No 543/2008, in conjunction with Annexes VI and VII thereto, constitute a requirement of ‘sound and fair marketable quality’ within the meaning of Article 28(1) of Commission Regulation (EC) No 612/2009 and of the judgment of the Court of Justice in *Nowaco Germany* (C-353/04, EU:C:2006:522)?
2. Can frozen poultry with a water content exceeding the threshold laid down by Article 15 of Regulation (EC) No 543/2008, in conjunction with Annexes VI and VII thereto, accompanied by a health certificate issued by the competent authority, be marketed within the European Union in normal conditions, within the meaning of Article 28 of Regulation (EC) No 612/2009, and, if so, in what conditions?
3. Is the fact that the water-content threshold remains at 5.1% under Annex VI to Regulation (EC) No 543/2008, and has not been revised for several decades, despite alleged changes in rearing practices and criticism in certain scientific studies that that threshold is obsolete, compatible or incompatible with EU law, and in particular with the principle of legal certainty?
4. Are Annexes VI and VII to Regulation (EC) No 543/2008 sufficiently precise for the checks provided for by Article 15 of that regulation to be carried out, or was France under an obligation to lay down ‘practical measures for the checks “at all stages of marketing’, failing which checks carried out at the stage of exportation of the goods cannot be relied upon?
5. Can the requests for counter-analyses which are provided for by Article 16(2) and (5) of Regulation No 543/2008 in respect of the results of slaughterhouse checks be extended to checks carried out at the stage of marketing of export products, in the presence of the parties, pursuant to, inter alia, Article 41 of the Charter of Fundamental Rights of the European Union?

The judgement of the Court of Justice⁴⁶⁸ upheld the current law and confirmed that frozen or quick-frozen chickens with a water content exceeding the limits are not marketable in the EU and do not satisfy the requirement of sound and fair marketable quality. However the Court affirmed that an exporter of frozen or quick-frozen chickens may be present or represented when the goods are examined and when samples are taken and may request a further examination or sampling of the goods if he considers that the results obtained by the competent authorities are not valid.

The Court summarised its findings thus:⁴⁶⁹

1. The examination of the third question did not bring to light any evidence able to affect the validity of the limits for water content in frozen chicken meat laid down in Article 15(1) and Annexes VI and VII to Commission Regulation (EC) No 543/2008 of 16 June 2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultrymeat, as amended by Commission Implementing Regulation (EU) No 1239/2012 of 19 December 2012.
2. Article 28(1) of Commission Regulation (EC) No 612/2009 of 7 July 2009 on laying down common detailed rules for the application of the system of export refunds on agricultural products, as amended by Commission Regulation (EU) No 173/2011 of 23 February 2011, must be interpreted as meaning that frozen or quick-frozen chickens with a water content exceeding the limits set by Regulation No 543/2008, as amended by Implementing

⁴⁶⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2015.190.01.0004.01.ENG&toc=OJ:C:2015:190:TOC

⁴⁶⁸ <http://curia.europa.eu/juris/document/document.jsf?docid=188754&doclang=en>

⁴⁶⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.144.01.0002.01.ENG&toc=OJ:C:2017:144:TOC#ntr1-C_2017144EN.01000201-E0001

- Regulation No 1239/2012, are not marketable in normal conditions on the territory of the European Union and do not satisfy the requirement of sound and fair marketable quality, even if they are accompanied by a health certificate issued by the competent authority.
3. Since Annexes VI and VII to Regulation No 543/2008, as amended by Implementing Regulation No 1239/2012, are sufficiently precise for the purpose of carrying out the checks on frozen and quick-frozen chickens intended for export with export refunds, the fact that a Member State has not adopted practical measures, whose adoption is provided for in Article 18(2) of that regulation, does not prevent those checks from being relied on against the undertakings concerned.
 4. An exporter of frozen or quick-frozen chickens may, in accordance with Article 118(2) and Article 119(1), second subparagraph, of Regulation (EC) No 450/2008 of the European Parliament and of the Council of 23 April 2008 laying down the Community Customs Code (Modernised Customs Code) may, first, be present or represented when the goods are examined and when samples are taken and, second, may request a further examination or sampling of the goods if he considers that the results obtained by the competent authorities are not valid.

3.4 Genetically modified organisms (GMO)

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.⁴⁷⁰

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.⁴⁷¹ Labelling, environmental and post-market monitoring, a detection method and reference material are normally detailed in the Decisions.

Commission Directive (EU) 2018/350 of 8 March 2018 amended Directive 2001/18/EC of the European Parliament and of the Council to update statutory guidance on the environmental risk assessment of GMOs.⁴⁷²

In a judgment of the European Court (Third Chamber) of 13 September 2017 (Case C-111/16) the court held that Member States cannot adopt interim emergency measures on GMOs solely on the basis of the 'precautionary principle', without appropriate conditions being satisfied (... likely to constitute a serious risk to human health, animal health or the environment). (Article 34 of Regulation No 1829/2003, read in conjunction with the precautionary principle as set out in Article 7 of Regulation No 178/2002).⁴⁷³ This was emphasised by a similar ruling in the Order of the Court (Third Chamber) of 23 November 2017 (request for a preliminary ruling from the Tribunale di Pordenone, Italy), Criminal proceedings against Giorgio Fidenato, (Case C-107/16).⁴⁷⁴

However, the Court of Justice of the EU ruled in Case T-33/16, TestBioTech eV, (Munich, Germany) v European Commission, that the health impacts of GMOs could be challenged

⁴⁷⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1436450297142&uri=CELEX:02003R1829-20080410>

⁴⁷¹ http://ec.europa.eu/food/plant/gmo_en

⁴⁷² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.067.01.0030.01.ENG&toc=OJ:L:2018:067:TOC

⁴⁷³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.382.01.0016.01.ENG&toc=OJ:C:2017:382:TOC

⁴⁷⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.032.01.0004.01.ENG&toc=OJ:C:2018:032:TOC

annulling the decision of the Commission to separate health issues from environmental issues.⁴⁷⁵⁻⁴⁷⁷

Five GM events were re-authorised in August 2018 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. The usual conditions were placed on the labelling and use. Commission Implementing Decision (EU) 2018/1109⁴⁷⁸ of 3 August⁴⁷⁹ 2018 renewed the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7). Commission Implementing Decision (EU) 2018/1110⁴⁸⁰ of 3 August 2018 authorised the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603, and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603, and repealed Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU. [The document number was subsequently corrected from C(2018) 4937) to C(2018) 4973]].⁴⁸¹ Commission Implementing Decision (EU) 2018/1111⁴⁸² of 3 August 2018 authorised the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89034-3 × MON-ØØ6Ø3-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealed Decision 2010/420/EU. Commission Implementing Decision (EU) 2018/1112⁴⁸³ of 3 August 2018 renewed the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 (MON-ØØØ21-9. Commission Implementing Decision (EU) 2018/1113⁴⁸⁴ of 3 August 2018 renewed the authorisation for the placing on the market of food and feed produced from genetically modified sugar beet H7-1 (KM-ØØØH71-4).

3.4.1 Genome editing

A significant case concerning genome editing before the Court of Justice of the European Union, (CJEU), on 25 July 2018 was reported in September 2018.⁴⁸⁵

Genome editing, in brief, is the deliberate alteration of a selected DNA sequence in a living cell. A strand of DNA is cut at a specific point and naturally existing cellular repair mechanisms then fix the broken DNA strands. The way they are repaired can affect gene function. New DNA sequences can be delivered when the DNA is cut and the cut segments act as templates for generating an altered sequence. Genome editing techniques can be used to delete sections of DNA or alter how a gene functions. The techniques make use of certain proteins discovered in the 1960s that can cut DNA in a precise, targeted location. However it is only since around 2005 that the ability to make precisely targeted cuts has been utilised. Among the recent genome editing technologies, CRISPR-based methods appear particularly promising. CRISPR-Cas9 is a widely used genome editing method and it has two components. CRISPR stands for 'clustered regularly interspaced short palindromic repeats'. This refers to the basis of the 'guide system' that

⁴⁷⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62016TJ0033>

⁴⁷⁶ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.152.01.0026.01.ENG&toc=OJ:C:2018:152:TOC

⁴⁷⁷ <https://www.clientearth.org/cjeu-rules-against-the-commission-the-health-impacts-of-gmos-can-be-challenged-under-the-aarhus-regulation/>

⁴⁷⁸ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.203.01.0007.01.ENG&toc=OJ:L:2018:203:TOC

⁴⁷⁹ Corrected from 1st to 3rd August by Corrigendum: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.221.01.0004.01.ENG&toc=OJ:L:2018:221:TOC

⁴⁸⁰ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.203.01.0013.01.ENG&toc=OJ:L:2018:203:TOC

⁴⁸¹ Corrigendum: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.221.01.0004.02.ENG&toc=OJ:L:2018:221:TOC

⁴⁸² https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.203.01.0020.01.ENG&toc=OJ:L:2018:203:TOC

⁴⁸³ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.203.01.0026.01.ENG&toc=OJ:L:2018:203:TOC

⁴⁸⁴ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.203.01.0032.01.ENG&toc=OJ:L:2018:203:TOC

⁴⁸⁵ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.328.01.0004.02.ENG&toc=OJ:C:2018:328:TOC

finds the 'target' – the specific sequence of the DNA that is to be modified. Cas9 stands for 'CRISPR-associated protein 9', the protein that cuts the DNA at the target site.⁴⁸⁶

The case, which centres on 'mutagenesis' which encompasses genome editing, was referred for a preliminary ruling to the CJEU by a French national court hearing proceedings by a French agricultural union and eight Non-Governmental Organisations (the applicants) against the French Prime Minister and the Minister for Agriculture, the Food Processing Industry and Forestry. The proceedings concern government refusal to revoke French national legislation according to which organisms obtained by mutagenesis are not, in principle, considered to result in genetic modification, and the refusal to ban the cultivation and marketing of herbicide-tolerant rape varieties obtained by mutagenesis.

The CJEU preliminary ruling was sought on the interpretation and validity of Articles 2 and 3 of, and of Annexes I A and I B to, Directive 2001/18/EC *on the deliberate release into the environment of genetically modified organisms* as well as the interpretation of Article 4 of Council Directive 2002/53/EC *on the common catalogue of varieties of agricultural plant species* as amended.

In summary, the CJEU held that organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive. However, organisms obtained by mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record are exempt from those obligations, on the understanding that the Member States are free to subject them, in compliance with EU law, to the obligations laid down by the GMO directive or to other obligations.⁴⁸⁷

The full judgement⁴⁸⁸ makes interesting reading. The CJEU relied heavily on information provided to it by the referring French court handling the main proceedings. In the French court the applicants submitted *inter alia* that mutagenesis techniques have evolved to make it possible to produce, as with transgenesis techniques, herbicide-resistant varieties which present risks for the environment or health. The French government submitted the alleged risks are the result not of the properties of the plant obtained through genetic modification, but of the growers' cultivation practices. Moreover, the mutations obtained by the new techniques of directed mutagenesis are similar to spontaneous or randomly introduced mutations and unintentional mutations can be eliminated in the varietal selection by crossing techniques.

The French court considered a number of issues including:

- (a) Conventional *in vivo* mutagenesis methods were used for several decades without creating identified risks for the environment or health. By contrast, since the adoption of Directive 2001/18, new varieties, in particular those resistant to herbicides, have been obtained through random mutagenesis techniques applied *in vitro* to plant cells and through directed mutagenesis techniques/methods applying new genetic engineering techniques, such as oligonucleotide-directed mutagenesis or directed nuclease mutagenesis.
- (b) It is impossible to determine with certainty the existence and extent of the risks presented by those new herbicide-resistant varieties for the environment and human and animal health, the only extant risk assessments being for the marketing authorisation for the herbicides to which those varieties have been made resistant.

⁴⁸⁶ Nuffield Council on Bioethics: Genome editing in brief: <http://nuffieldbioethics.org/report/genome-editing-ethical-review/genome-editing>

⁴⁸⁷ <https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf>

⁴⁸⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62016CJ0528>

- (c) That the risks are in part similar to those that might result from seeds produced by transgenesis.
- (d) The direct modification of the genome that the technique involves would result in the same effects as the introduction of a foreign gene, specific to transgenesis.
- (e) In addition, since the development of the new techniques of mutagenesis allows the production of modifications of the genetic heritage to increase at a rate out of all proportion to the modifications likely to occur naturally or randomly, the possibility of harm occurring as a result of unintentional modifications of the genome or of the properties of the plant thus obtained would be increased.

Thus the court decided to stay the proceedings and to refer the following questions to the CJEU for a preliminary ruling.

1. Do organisms obtained by mutagenesis constitute [GMOs] within the meaning of Article 2 of Directive 2001/18, although they are exempt under Article 3 of and Annex I B to the directive from the obligations laid down for release and placing on the market of [GMOs]? Specifically, may mutagenesis techniques, in particular new directed mutagenesis techniques implementing genetic engineering processes, be regarded as techniques listed in Annex I A, to which Article 2 refers? Consequently, must Articles 2 and 3 of and Annexes I A and I B to Directive [2001/18] be interpreted as meaning that they exempt from precautionary, impact-assessment and traceability measures all organisms and seeds obtained by mutagenesis, or only organisms obtained by conventional random mutagenesis methods by ionising radiation or exposure to mutagenic chemical agents existing before those measures were adopted?
2. Do varieties obtained by mutagenesis constitute genetically modified varieties within the meaning of Article 4 of Directive [2002/53] which would not be exempt from the obligations laid down in that directive? Or, on the contrary, is the scope of that directive the same as that under Articles 2 and 3 of and Annex I B to [Directive 2001/18], and does it also exempt varieties obtained by mutagenesis from the obligations laid down for the inclusion of genetically modified varieties in the common catalogue of agricultural plant species by [Directive 2002/53]?
3. Do Articles 2 and 3 of and Annex I B to Directive [2001/18] on the deliberate release into the environment of [GMOs] constitute, in so far as they exclude mutagenesis from the scope of the obligations laid down in the directive, a full harmonisation measure prohibiting Member States from subjecting organisms obtained by mutagenesis to all or some of the obligations laid down in the directive or to any other obligation, or do the Member States, when transposing those provisions, have a discretion to define the regime to be applied to organisms obtained by mutagenesis?
4. May the validity of Articles 2 and 3 of and Annexes I A and I B to Directive [2001/18] with regard to the precautionary principle guaranteed by Article 191(2) [TFEU⁴⁸⁹], in that those provisions do not subject [GMOs] obtained by mutagenesis to precautionary, impact-assessment and traceability measures, be called into question, taking account of the development of genetic engineering processes, the appearance of new plant varieties obtained by means of those techniques and the current scientific uncertainty as to their impacts and the potential risks they represent for the environment and human and animal health?

Question 1

⁴⁸⁹ Treaty on the Functioning of the European Union, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT>

The CJEU noted Article 2(2) of Directive 2001/18 defines a GMO as “ ... an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.” The CJEU held that the mutations brought about by techniques of mutagenesis at issue in the main proceedings involve the use of chemical or physical mutagenic agents, or the use of genetic engineering, and are intended to produce herbicide-resistant varieties of plant species. The mutations thus constitute alterations made to the genetic material of an organism, for the purposes of Article 2(2) of Directive 2001/18, and in a way that does not occur naturally, within the meaning of that provision. It follows that organisms obtained by means of techniques of mutagenesis must be considered to be GMOs within the meaning of Article 2(2) of Directive 2001/18.

The CJEU went on to consider the inclusions and exclusions from the GMO definition set out in Annex I of the Directive:

- In **Annex I A Part 1** GM techniques are listed as **including** *inter alia*: recombinant nucleic acid techniques ..., techniques involving the direct introduction into an organism of heritable material prepared outside the organism ..., and cell fusion or hybridisation techniques.
- **Annex I A Part 2** lists techniques (e.g. *in vitro* fertilisation or natural processes ...) not considered to result in genetic modification, with conditions – that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B.
- **Annex I B states:**

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

- (1) mutagenesis,
- (2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

Thus on the face of it mutagenesis might not be regarded as producing a GMO. However the CJEU noted that the “*inter alia*” in the list of GMO techniques in Annex I A Part 1 means that list is *not exhaustive* [and thus could include mutagenesis]. However the list of techniques that do *not* produce GMOs in Annex I A Part 2 is *exhaustive* [and does not cite mutagenesis]. The CJEU considered that as ‘mutagenesis’ was mentioned generally no conclusive guidance was provided in the body of Directive 2001/18. Thus the CJEU clearly felt able to consider in more detail the nature of mutagenesis in the context of the recitals to the Directive. In particular the CJEU drew attention to Recital 17 (“... Directive 2001/18 should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record”), and noted that the French court was called upon to rule on ... directed mutagenesis ... mostly developed since Directive 2001/18 was adopted and in respect of which the risks for the environment or for human health have not thus far been established with certainty. Recital 4 of the Directive notes the risks of releases into the environment may be irreversible and Recital 8 invokes the ‘precautionary principle’.

Thus the CJEU held that Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive and in the light of recital 17 mean that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive.

Question 2

Having decided question 1 in the way that it did, the CJEU discussed the application of obligations under Article 4 of Directive 2002/53 at less length. However in the light of other provisions and case law Article 4(4) of Directive 2002/53 means that [only] genetically modified varieties obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are exempt from the obligations laid down in that provision.

Question 3

The CJEU held that organisms obtained by means of mutagenesis techniques conventionally used in a number of applications and with a long safety record do not come within the scope of Directive 2001/18, and EU legislation does not specify the legal regime to which they may be subject. It does not follow however that deliberate release into the environment or placement on the market could freely take place. Thus Member States cannot be denied the option of subjecting such organisms, in compliance with EU law, (e.g. rules on the free movement of goods) to the obligations laid down in Directive 2001/18 or to other obligations.

Question 4

Having concluded that not all mutagenesis techniques are excluded from the provisions of Directive 2001/18 the CJEU held that an answer to the fourth question was not necessary.

The National Court

It is for the national court to dispose of the case in accordance with the CJEU decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

3.4.2 Cultivation of GMOs

Commission Directive 2015/412⁴⁹⁰ 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 report⁴⁹¹ for further details.

3.5 Cloned animals

Cloning involves the removal of the nucleus from a somatic cell (any body tissue) of an animal and its transfer into an enucleated egg (an egg cell that has had its own nucleus removed) of a donor female of the same species. This is then stimulated to generate an embryo for transfer into a surrogate mother. In April 2016 the Defra Farm Animal Genetic Resources Committee issued a statement on cloning of farm animals. EU legislation regards foods and food ingredients derived from clones as novel foods. However, the European Commission and both EFSA and the UK's FSA acknowledge that meat and milk from healthy clones and healthy offspring of clones is indistinguishable from, and as safe as that from, conventionally bred animals. The Defra Committee did not consider that there is any scientific justification for treating the products of the healthy offspring of clones, including semen and embryos, any differently from conventionally bred animals with regard to the production of food. The Committee noted that, in past trials, some cloned progeny have not developed normally, leading to significant welfare problems and premature death.⁴⁹²

⁴⁹⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.068.01.0001.01.ENG

⁴⁹¹ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2015>

⁴⁹² https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/524769/fanqr-cloning-farm-animals-statement.pdf

In September 2015 the European Parliament adopted at first reading a draft directive prohibiting cloning of farmed bovine, porcine, ovine, caprine or equine animals, based largely on animal welfare concerns. In September 2017 this was recast as a draft regulation.⁴⁹³

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.⁴⁹⁴ This appears still to be the case.

3.6 Novel foods

Novel foods and novel food ingredients are regulated by Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015⁴⁹⁵ which replaced previous regulations on 1 January 2018. A Commission Q&A is available⁴⁹⁶ and a list of authorisations.⁴⁹⁷ 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 2016.⁴⁹⁸

Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017⁴⁹⁹ lists EU novel foods authorised to date in accordance with Regulation 2015/2283 together with the conditions under which the novel food may be used, including maximum levels if applicable, any specific labelling requirements and any other requirements.

Commission Implementing Regulation (EU) 2018/1023⁵⁰⁰ of 23 July 2018 updated the current EU list of novel foods under Implementing Regulation (EU) 2017/2470.

The procedural steps and information required to assess a food as a novel food are set out in Commission Implementing Regulation (EU) 2018/456 of 19 March 2018.⁵⁰¹

In February 2018 EFSA published new administrative guidance to help applicants to prepare novel food applications. The guidance includes a checklist of the data requirements.⁵⁰²

The Novel Foods (Wales) Regulations 2017 were made on 14 November 2017,⁵⁰³ coming into force on 1 January 2018. The Regulations provide for the execution and enforcement in Wales of Regulation (EU) 2015/2283. The Regulations make food authorities responsible for their enforcement and provide that it is an offence for a person to fail to comply with Article 6(2) of the Regulation 2015/2283 by which only novel foods authorised by the Commission and included in the EU list of novel foods may be placed on the market. The foods must be in accordance with conditions of use and the labelling requirements set out in the list. Certain provisions of the Food Safety Act 1990 apply including enabling an authorised officer, if non-compliance is found, to give

⁴⁹³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.316.01.0278.01.ENG&toc=OJ:C:2017:316:TOC

⁴⁹⁴ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/332618/Cloned_animal_report.pdf

⁴⁹⁵ 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

⁴⁹⁶ http://europa.eu/rapid/press-release_MEMO-15-5875_en.htm

⁴⁹⁷ http://ec.europa.eu/food/safety/novel_food/authorisations/list_authorisations/index_en.htm

⁴⁹⁸ <https://www.efsa.europa.eu/en/press/news/161110>

⁴⁹⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.351.01.0072.01.ENG&toc=OJ:L:2017:351:TOC

⁵⁰⁰ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.187.01.0001.01.ENG&toc=OJ:L:2018:187:TOC

⁵⁰¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.077.01.0006.01.ENG&toc=OJ:L:2018:077:TOC

⁵⁰² https://www.efsa.europa.eu/en/press/news/180216?utm_campaign=engagor&utm_content=engagor_MzgyMTE2MA%3D%3D&utm_medium=social&utm_source=twitter

⁵⁰³ <http://www.legislation.gov.uk/wsi/2017/1103/contents/made>

a notice that the food is not to be used for human consumption or is not to be removed except to some place specified in the notice, or to seize the food in order to have it dealt with by a justice of the peace; and enabling an improvement notice to be served requiring the person in charge of the food to comply with the provisions of the Novel Foods Regulation specified in Schedule 1 to these Regulations. The provisions, as applied, make the failure to comply with an improvement notice an offence. The Novel Foods and Novel Food Ingredients Regulations 1997 in relation to Wales, the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 in relation to Wales and the Food Enzymes (Wales) Regulations 2009 are revoked.

Similar provisions were made in the Novel Foods (Scotland) Regulations 2017,⁵⁰⁴ and the Novel Foods Regulations (Northern Ireland) 2017⁵⁰⁵ both also coming into force on 1 January 2018 with equivalent revocations.

In February 2018 the Novel Foods (England) Regulations 2018⁵⁰⁶ were made coming into force on 8 March 2018. These regulations contain equivalent provisions to the above regulations in the devolved areas and revoke the Novel Foods and Novel Food Ingredients Regulations 1997 (S.I. 1997/1335) and the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 (S.I. 1997/1336) in relation to England.

Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017⁵⁰⁷ laid down administrative and scientific requirements concerning traditional foods from third countries. The scientific data to be provided in a notification or an application (Article 6) consist of a dossier from the third country to enable a history of safe use of the traditional food to be assessed, the procedure followed when gathering the data, the safety evaluation strategy justifying the inclusion or exclusion of specific studies or information and an overall conclusion on the safety of the proposed uses of the traditional food. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017⁵⁰⁸ laid down administrative and scientific requirements for applications for novel food authorisation within the EU. The scientific data requirements (Article 5) to be provided in support include a dossier to enable a comprehensive risk assessment of the novel food. Where the application involves the use of engineered nanomaterials the applicant must provide detection and characterisation test methods.

The applicant must provide documentation on the procedure and strategy followed when gathering the dossier data, along with a description of the safety evaluation and toxicological testing strategies, and justify the inclusion or exclusion of specific studies or information. The applicant must also provide on request the raw data for the individual studies, published and unpublished, to support their application. Where it cannot be excluded that a novel food intended for a particular group of the population would be also consumed by other groups of the population the safety data provided shall also cover those groups. For each biological or toxicological study, the applicant shall clarify whether the test material conforms to the proposed or existing specification. Where the test material differs from that specification, the applicant shall demonstrate the relevance of those data to the novel food under consideration. Toxicological studies must be conducted in facilities which comply with the requirements of Directive

⁵⁰⁴ <http://www.legislation.gov.uk/ssi/2017/415/contents/made>

⁵⁰⁵ <http://www.legislation.gov.uk/nisr/2017/233/introduction/made>

⁵⁰⁶ <http://www.legislation.gov.uk/uksi/2018/154/contents/made>

⁵⁰⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.351.01.0055.01.ENG&toc=OJ:L:2017:351:TOC

⁵⁰⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.351.01.0064.01.ENG&toc=OJ:L:2017:351:TOC

2004/10/EC or, if they are carried out outside the EU, follow the OECD Principles of Good Laboratory Practice. The applicant must provide evidence of compliance with those requirements and justify any deviation from the standard protocols. The applicant must propose an overall conclusion on the safety of the proposed uses of the novel food with an overall evaluation of potential risk to human health in the context of known or likely human exposure.

Summaries of novel foods authorised in 2017 and the first half of 2018 are given in Section 3.6 of our April to June 2018 report.⁵⁰⁹ In the period July to September nine novel foods were authorised or their use extended.

Commission Implementing Regulation (EU) 2018/991⁵¹⁰ of 12 July 2018 authorised the use of hen egg white lysozyme hydrolysate as a novel food in food supplements under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amended Commission Implementing Regulation (EU) 2017/2470. A specification is included in the regulation.

Commission Implementing Regulation (EU) 2018/1011 of 17 July 2018 authorised an extension, owing to increased vitamin D of use levels of UV-treated mushrooms as a novel food under Regulation (EU) 2015/2283. The designation on the label of the novel food as such or of the foodstuffs containing it shall be “UV-treated mushrooms (*Agaricus bisporus*)” and shall be accompanied by indication that a “controlled light treatment was used to increase vitamin D levels’ or ‘UV treatment was used to increase vitamin D2 levels”.’ A maximum of 20 µg of vitamin D₂ per 100 g fresh weight is permitted.

Commission Implementing Regulation (EU) 2018/1018 of 18 July 2018⁵¹¹ authorised an extension of use of UV-treated baker’s yeast (*Saccharomyces cerevisiae*) as a novel food to pre-packed fresh and dry yeast for home baking and in food supplements. In addition, the lower specification of the vitamin D₂ content in the yeast concentrate from 1 800 000 IU (450 µg/g) to 800 000 IU (200 µg/g) was approved. The designation on the labelling of the foodstuffs containing it shall be “Vitamin D yeast” or “Vitamin D₂ yeast”. For home baking the labelling shall bear a statement that the foodstuff is only intended for baking and that it should not be eaten raw with instructions for use for the final consumers so that a maximum concentration of 5 µg/100 g of vitamin D₂ in final home-baked products is not exceeded. Maxima for vitamin D₂ and a specification are given.

Commission Implementing Regulation (EU) 2018/1032⁵¹² of 20 July 2018 authorised the extension of use of oil from the micro algae *Schizochytrium* sp. as a novel food. Multiple applications had been received for extension from previously authorised strains of the micro algae to a different strain and extend its use to fruit and vegetable purees. The oil contains docosahexaenoic acid (DHA) an omega-3 fatty acid said to be important for health. The designation of the novel food on the labelling of the foodstuffs containing it shall be “Oil from the microalgae *Schizochytrium* sp.” Maximum use levels in a variety of foods and maximum DHA concentrations in supplements are given.

Commission Implementing Regulation (EU) 2018/1122⁵¹³ of 10 August 2018 authorised the placing on the market of pyrroloquinoline quinone disodium salt as a novel food⁵¹⁴ for use in food

⁵⁰⁹ [Foodfeedlaw_Apr_June2018.pdf](#)

⁵¹⁰ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.177.01.0009.01.ENG&toc=OJ:L:2018:177:TOC

⁵¹¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.183.01.0009.01.ENG&toc=OJ:L:2018:183:TOC

⁵¹² https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.185.01.0009.01.ENG&toc=OJ:L:2018:185:TOC

⁵¹³ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.204.01.0036.01.ENG&toc=OJ:L:2018:204:TOC

⁵¹⁴ Turck *et al.*, 2017, EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), EFSA Journal 2017;15(11):5058, <https://www.efsa.europa.eu/en/efsajournal/pub/5058>

supplements to a maximum intake of 20 mg per day. The food supplement should be consumed by adults only excluding pregnant and lactating women. Disodium pyrroloquinoline quinone has been studied as a compound with strong antioxidant capacity and for its effects on serum lipid levels.⁵¹⁵

Commission Implementing Regulation (EU) 2018/1123⁵¹⁶ of 10 August 2018 authorised the placing on the market of 1-methylnicotinamide chloride as a novel food for use in food supplements to a maximum intake of 58 mg per day for adults only, excluding pregnant and lactating women.

Commission Implementing Regulation (EU) 2018/1133⁵¹⁷ of 13 August 2018 authorised the placing on the market of dried aerial parts of *Hoodia parviflora* as a novel food for use in food supplements to a maximum intake of 9.4 mg per day following an evaluation by EFSA.⁵¹⁸ The marketed form is the dried powdered whole aerial parts of *Hoodia parviflora* N.E.Br., (family *Apocynaceae*). Species of *Hoodia*, a southern African succulent plant, have been studied for their appetite suppressing properties.⁵¹⁹

Commission Implementing Regulation (EU) 2018/1132⁵²⁰ of 13 August 2018 authorised removal of the word 'synthetic' from the designation and specific labelling the novel food previously authorised as 'synthetic zeaxanthin' following representations from the applicant company. The company argued that there was a potential negative economic impact with the use of the term 'synthetic'. The Commission took into account that there are a number of synthetic substances currently authorised and listed in the EU list of novel foods with naturally occurring counterparts and both forms are used in food supplements. However those synthetic substances are not designated as synthetic in the EU list and are not labelled as such. The change in the designation and labelling of synthetic zeaxanthin to remove the word 'synthetic' thus ensures consistency.

Commission Implementing Regulation (EU) 2018/1293 of 26 September 2018 amended Implementing Regulation (EU) 2017/2470 to allow the previously authorised novel food lactitol to be used in powder form in food supplements to the previously permitted maximum of 20 g per day.⁵²¹

It is occasionally necessary to appraise a food product that purports to represent a traditional recipe possibly unfamiliar to a UK based analyst. In this regard a publication from the Food and Agriculture Organization, 'Recipe book: health, knowledge and flavours'⁵²² may be of interest. The book is a compilation of 23 recipes used by women from 20 countries in Latin America and the Caribbean.

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

⁵¹⁵ See for example Nakano, M., Kawasaki, Y., Suzuki, N. and Takara, T., 2015. Effects of pyrroloquinoline quinone disodium salt intake on the serum cholesterol levels of healthy Japanese adults. *Journal of nutritional science and vitaminology*, 61(3), pp.233-240.

⁵¹⁶ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.204.01.0041.01.ENG&toc=OJ:L:2018:204:TOC

⁵¹⁷ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.205.01.0018.01.ENG&toc=OJ:L:2018:205:TOC

⁵¹⁸ Turck *et al.*, 2017, EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), EFSA Journal 2017;15(10):5002, 21 pp, <https://doi.org/10.2903/j.efsa.2017.5002>

⁵¹⁹ See e.g. Landor, M., Benami, A., Segev, N. and Loberant, B., 2015. Efficacy and acceptance of a commercial Hoodia parviflora product for support of appetite and weight control in a consumer trial. *Journal of medicinal food*, 18(2), pp.250-258.

⁵²⁰ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.205.01.0015.01.ENG&toc=OJ:L:2018:205:TOC

⁵²¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.243.01.0002.01.ENG&toc=OJ:L:2018:243:TOC

⁵²² <http://www.fao.org/3/i8269en/l8269EN.pdf>

3.7 Consumer attitudes

The FSA publishes regular reports of surveys into information about the public's self-reported behaviours, attitudes and knowledge relating to food issues. The latest such report, published on 1 August 2018 showed the top food safety issues of concern for respondents were:

- Food hygiene when eating out (33%)
- Chemicals from the environment, such as lead, in food (30%)
- Food additives (29%)
- Food poisoning (28%)

The top wider food issues of concern were:

- The amount of sugar in food (55%)
- Food waste (51%)
- Food prices (43%)
- Animal welfare (42%)
-

There was concern about food safety in UK food outlets - 45% of respondents reported concern about food safety in UK restaurants, pubs, cafes and takeaways and 43% of respondents reported concern about food safety in UK shops and supermarkets.

Awareness of hygiene standards was high with 82% of respondents reported that they were aware of hygiene standards in places they eat out at or buy food from. The most commonly reported ways of knowing about hygiene standards were via hygiene stickers / certificates and the general appearance of the premises (both 61%).

The findings demonstrate that 79% of respondents reported being aware of the FSA, similar to previous waves. Of those aware of the FSA, 69% trusted the FSA to do its job, and 72% trusted the FSA to tell the truth in the information it provides. As with previous waves, the main issue respondents thought the FSA was responsible for was ensuring food bought is safe to eat (89%).

Not surprisingly there was awareness of food poisoning. *Salmonella* and *E. coli* were by far the most commonly known types of food poisoning (total awareness of 91% and 85% respectively). Perceived most likely sources of food poisoning were raw chicken or turkey (79%), followed by shellfish (55%), reheated take-away food (46%) and eggs (37%).

On food allergens, 15% of respondents were aware of specific rules about allergens, and 11% reported that they have a food intolerance and / or allergy themselves. Most people (71%-78%) reported feeling confident to ask a member of staff at food outlets for more information about ingredients in food because of a concern about possible allergens / food intolerance.

Attitudes towards food production, sale and labelling were also surveyed with the majority reporting that they trust that food is 'what it says it is' and is accurately labelled (75%) and 73% trusted the authenticity of ingredients / origin / quality of food. Findings also demonstrated that 41% of respondents trusted that people who produce and sell food have their best interests at heart.

The full report, 'Biannual Public Attitudes Tracker', Wave 16, May 2018, Food Standards Agency August 2018 is available.⁵²³ Details of previous surveys are included in our April to June 2018 report.⁵²⁴

⁵²³ <https://www.food.gov.uk/news-alerts/news/public-attitudes-tracker-survey-results-published-0>

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.^{525, 526}

A correction slip to the Consumer Rights Act 2015 was issued in October 2017.⁵²⁷

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.⁵²⁸

Guidance on nutrition labelling is available on the Commission website.⁵²⁹ Commission Regulation (EU) No 432/2012 established the list of permitted health claims and started to apply from 14 December 2012.⁵³⁰ The EU Register of nutrition and health claims is also available⁵³¹ hence successive amendments to Regulation 432/2012 are not usually recorded here unless a change is made that requires further explanation.

See also a 2017 publication that summarises current issues in nutrition and health claims that arose in a seminar on the enforcement of such claims.⁵³² An issue that was mentioned in the seminar was the taking down of websites that host alleged illegal claims.

Commission Recommendation (EU) 2018/334 of 1 March 2018 discusses measures to effectively tackle illegal content online.⁵³³

⁵²⁴ [Foodfeedlaw_Apr_June2018.pdf](#)

⁵²⁵ <https://www.gov.uk/government/publications/consumer-rights-act-2015/consumer-rights-act-2015>

⁵²⁶ <http://www.which.co.uk/consumer-rights/regulation/consumer-rights-act>

⁵²⁷ http://www.legislation.gov.uk/ukpga/2015/15/pdfs/ukpgacs_20150015_en.pdf

⁵²⁸ http://ec.europa.eu/food/safety/labelling_nutrition/claims/refit/index_en.htm

⁵²⁹ http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm

⁵³⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012R0432>

⁵³¹ http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/index_en.htm

⁵³² Walker, M. J. (2017), Health and nutrition claims – guidance, regulation and self-regulation, Nutrition Bulletin, 42: 69-79

⁵³³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.063.01.0050.01.ENG&toc=OJ:L:2018:063:TOC

An example of the complexities of nutrition claims regulation occurred in August 2016 when Commission Regulation (EU) 2016/1413⁵³⁴ amended Regulation (EU) No 432/2012 in respect of two claims authorised for meal replacement for weight control. The conditions of use of those claims require that in order to bear them, the food should contain a maximum of 250 kcal per serving and comply with specifications laid down in Directive 96/8/EC. However Directive 96/8/EC has been replaced by Regulation 609/2013 (see Section 4.2) therefore, the references to Directive 96/8/EC needed to be replaced. Regulation 1169/2011 on the provision of food information to consumers (see Section 3.1) sets out nutrient reference values for vitamins and minerals that differ from some of those in Directive 96/8/EC.

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

Regular bulletins are available from the Department of Health on EU legislation on nutrition and health claims.⁵³⁵

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 2019.⁵³⁶

4.1.1 Cases in the Court of Justice of the European Union

4.1.1.1 Ability to withhold authorisation despite EFSA favourable opinion

In an interesting case the European Court upheld the refusal of the Commission to authorise a series of health claims despite favourable EFSA opinions. The claims related to the normal metabolism of glucose and its support of normal physical activity. The Commission relied upon Regulation (EC) No 1924/2006 powers to withhold authorisation if health claims do not comply with general and specific requirements of the Regulation even in the face of a favourable scientific assessment by EFSA. The glucose health claims, it was held, would convey a conflicting and confusing message to consumers, because it would encourage consumption of sugars for which, on the basis of generally accepted scientific advice, national and international

⁵³⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1413>

⁵³⁵ <https://www.gov.uk/government/publications/nutritional-and-health-claims-legislation-bulletins-2015>

⁵³⁶ <http://www.foodcomplianceinternational.com/blog/2017/2/15/new-belgian-belfrit-decree-on-botanicals-applicable>

authorities advise consumers to reduce their intake. Therefore, such claims contravene point (a) of the second paragraph of Article 3 of the Regulation that claims should not be ambiguous or misleading. The applicant company brought an action seeking the annulment of the regulation which was refused by the General Court (Fifth Chamber) on 16 March 2016. The company appealed the decision which was again dismissed with costs against the appellant in July 2017.⁵³⁷

4.1.1.2 On-hold botanical claims

The assessment of some botanical claims is 'on hold'⁵³⁸ 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).⁵³⁹⁻⁵⁴¹

On a similar theme the European Court (Third Chamber) issued a judgement on 23 November 2017⁵⁴² dismissing actions, Bionorica SE (C-596/15 P), Diapharm GmbH & Co. KG (C-597/15 P) against the European Commission, (Joined Cases C-596/15 P and C-597/15 P) for failure to act on botanical claims that remain 'on-hold'. The Commission argued that the actions did not have a proper purpose, lack of interest in bringing proceedings and lack of standing on the part of the applicant, Bionorica. The Court held that it was clear from the elements submitted by Bionorica before the General Court, that it did not carry on business as a manufacturer of food or food supplements on the European market. Bionorica was a manufacturer of herbal medicinal products, which are not covered by the provisions of Regulation No 1924/2006. Bionorica submitted that, given its presence on the market for herbal medicinal products containing the same botanical substances as those covered by the health claims on hold, it is ready to enter into the market for food supplements if the health claims in question are authorised. However, the Court held that a mere statement of intention, given that it refers to a future and uncertain situation, cannot suffice to establish Bionorica's current and vested interest in bringing proceedings. Consequently, without it being necessary to examine the other pleas of inadmissibility raised by the Commission, Bionorica's appeal in Case T-619/14 was dismissed as inadmissible. The full text of the judgement is available.⁵⁴³

4.1.2 Committee on Advertising Practice, CAP

The Committee of Advertising Practice (CAP) is the self-regulatory body that creates, revises and enforces the UK Code of Non-broadcast Advertising and Direct & Promotional Marketing⁵⁴⁴ (the CAP Code). The CAP Code covers marketing communications across all non-broadcast media including on marketers' own websites. The Broadcast Committee of Advertising Practice (BCAP) is the regulatory body responsible for maintaining the UK Code of Broadcast Advertising⁵⁴⁵ (the BCAP Code) under agreement with the Office of Communications (Ofcom). The BCAP Code regulates all advertisements on television channels and radio stations licensed by Ofcom and all advertisements on *Sianel Pedwar Cymru* (S4C) and S4C digital, including teleshopping channels

⁵³⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.249.01.0010.02.ENG&toc=OJ:C:2017:249:TOC

⁵³⁸ For further information see Walker, M. J. (2017), Health and nutrition claims – guidance, regulation and self-regulation. *Nutrition Bulletin*, 42, 69–79

⁵³⁹ 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

⁵⁴⁰ <http://curia.europa.eu/juris/document/document.jsf?docid=174170&doclang=en>

⁵⁴¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62015CO0637>

⁵⁴² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.022.01.0003.01.ENG&toc=OJ:C:2018:022:TOC

⁵⁴³ <http://curia.europa.eu/juris/document/document.jsf?docid=197043&doclang=EN>

⁵⁴⁴ <https://www.asa.org.uk/codes-and-rulings/advertising-codes/non-broadcast-code.html>

⁵⁴⁵ <https://www.asa.org.uk/codes-and-rulings/advertising-codes/broadcast-code.html>

and any additional television service (including television text services and interactive television services). These Advertising Codes are enforced by the Advertising Standards Authority ([ASA](#)) which investigates complaints and publishes rulings on complaints about individual ads each week⁵⁴⁶ in addition to conducting proactive work in relation to particular regulatory issues.

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 2007.⁵⁴⁷

CAP and BCAP aim to deliver transparent regulation which is evidence-based particularly in the absence of legislative imperatives. CAP and BCAP have offered guidance on their approach to regulatory change and the key factors which are likely to inform their thinking. It should be useful to those who wish to argue for regulatory change or better understand CAP and BCAP's approach to policy-making. CAP and BCAP keep their Codes under review and welcome new evidence, which can take many forms. CAP and BCAP do not prescribe study design but cite favourable aspects such as identification of the nature, scale and impact of any detriment, a recognised methodology, takes into account confounding variables, a representative cross-section of a relevant population and mitigates against potential bias. CAP and BCAP have drawn up non-exhaustive key points for those who are commissioning research or who aim to influence policy, discuss the legal context and how they might respond to submitted evidence.⁵⁴⁸

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

Regulation (EU) No 609/2013, which came fully into effect from 20 July 2016, lays down general compositional and information requirements for the above categories of food, including infant formula and follow-on formula. The Commission adopted specific compositional and information requirements for infant formula and follow-on formula, taking into account the provisions of Directive 2006/141/EC. Infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first months of life until the introduction of appropriate complementary feeding. In order to safeguard the health of those infants, it is necessary to ensure that infant formula is the only product marketed as suitable for such use during that period. The essential composition of infant formula and follow-on formula must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data. Infant formula and follow-on formula are sophisticated products that are specially formulated for a vulnerable group of consumers. In order to ensure the safety and suitability of such products, detailed requirements are laid down on the composition of infant formula and follow-on formula, including requirements on energy value, macronutrient and micronutrient content. These requirements are based on an EFSA opinion on the essential composition of infant and follow-on formulae. Commission Delegated Regulation 2016/127⁵⁴⁹ 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

⁵⁴⁶ <https://www.asa.org.uk/codes-and-rulings/rulings.html>

⁵⁴⁷ <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>

⁵⁴⁸ <https://www.asa.org.uk/uploads/assets/uploaded/cb20c00f-b559-40a2-8b5677188511b45b.pdf>

⁵⁴⁹ 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

and young child feeding. Commission Delegated Regulation 2016/128⁵⁵⁰ 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 2016.⁵⁵¹ 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 English⁵⁵² and Welsh⁵⁵³ 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 Ireland⁵⁵⁴ 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 1990.⁵⁵⁵

4.2.1 Total diet replacement for weight control

An attempt to introduce specific compositional and information requirements for total diet replacement for weight control under Regulation (EU) No 609/2013 was made with Commission Delegated Regulation (EU) 2017/1522 of 2 June 2017.⁵⁵⁶ However this was declared null and void⁵⁵⁷ on 6 September 2017, to be replaced in October 2017 by Commission Delegated

⁵⁵⁰ 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

⁵⁵¹ <http://www.legislation.gov.uk/ssi/2016/190/contents/made>

⁵⁵² The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016

http://www.legislation.gov.uk/ukxi/2016/688/pdfs/ukxi_20160688_en.pdf

⁵⁵³ The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016

<http://www.assembly.wales/laid%20documents/sub-ld10709/sub-ld10709-e.pdf>

⁵⁵⁴ The Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016

<http://www.legislation.gov.uk/nisr/2016/251/made>

⁵⁵⁵ <http://www.legislation.gov.uk/ukxi/2017/62/contents/made>

⁵⁵⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.230.01.0001.01.ENG&toc=OJ:L:2017:230:TOC

⁵⁵⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.234.01.0007.01.ENG&toc=OJ:L:2017:234:TOC

Regulation (EU) 2017/1798⁵⁵⁸ which provides that the product name under which food covered by Article 2(2)(h) of Regulation (EU) No 609/2013 is sold shall be 'total diet replacement for weight control'. Regulation (EU) 2017/1798 sets out (a) compositional requirements, (b) requirements for labelling, presentation and advertising and (c) notification requirements for placing the product on the market. The provisions permit the voluntary addition to total diet replacement for weight control products of ingredients not covered by specific requirements, with particular attention, for example, to dietary fibre. As regards labelling Article 30(2) of Regulation (EU) No 1169/2011 (Food Information to Consumers) lists a limited number of nutrients that may be included on a voluntary basis in the nutrition declaration for food. The Annex to Regulation (EU) No 609/2013 lists a series of substances that may be added to total diet replacement for weight control products, some of which are not covered by Article 30(2) of Regulation (EU) No 1169/2011. Thus for legal clarity, Regulation (EU) 2017/1798 lays down explicitly that the nutrition declaration for total diet replacement for weight control products may include such substances. Compositional requirements include vitamins and minerals, and protein quality in terms of the amino acid profile.

4.3 Sugar

Sugar continues to be a topic of keen current interest. In October 2015 Public Health England, PHE, published⁵⁵⁹ 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 26,⁵⁶⁰ 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.⁵⁶¹

PHE has engaged with all sectors of the food industry to reduce the amount of sugar in the foods that contribute most to children's intakes by 20% by 2020, with a 5% reduction in the first year.⁵⁶² Industry response was positive.⁵⁶³

⁵⁵⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.259.01.0002.01.ENG&toc=OJ:L:2017:259:TOC

⁵⁵⁹ <https://www.gov.uk/government/news/new-evidence-review-of-measures-to-reduce-sugar-consumption>

⁵⁶⁰ http://www.legislation.gov.uk/ni/2016/26/pdfs/ni_20160026_en.pdf

⁵⁶¹ <https://publichealthmatters.blog.gov.uk/2017/03/30/expert-interview-new-guidelines-for-industry-on-the-sugar-reduction-programme/>

⁵⁶² <https://www.gov.uk/government/collections/sugar-reduction>

⁵⁶³ <https://www.fdf.org.uk/news.aspx?article=7778&newsindexpage=3>

The government announced in the 2017 budget a proposal to introduce a soft drinks industry levy in April 2018. The new tax will be applied to soft drinks which contain added sugar, and have a total sugar content above certain thresholds. The government is introducing the levy in an effort to tackle obesity by reducing the consumption of drinks with added sugar, and to encourage manufacturers to reduce the sugar content of their products.^{564, 565}

The Soft Drinks Industry Levy Regulations 2018⁵⁶⁶ and the Soft Drinks Industry Levy (Enforcement) Regulations 2018⁵⁶⁷ were made in March 2018 coming into force on 6 April 2018 and apply throughout the UK. The Regulations make provision in relation to the soft drinks industry levy introduced by the Finance Act 2017 (c. 10) ('the Act'). The former contain detailed provisions including on dilution ratios, what is to be treated as fruit juice, what is to be treated as vegetable juice, or milk, define those drinks which are exempt, set out the conditions which must be met for a drink to be an alcohol substitute drink (which is exempt), and designate certain nutrition declarations for the purposes of Part 2 of the Act, further to section 59(3) of the Act. There are extensive administrative provisions. The latter regulations apply the provisions of the Customs and Excise Management Act 1979 (c. 2) ("CEMA 1979") for the purposes of enforcement of the levy.

Commission Implementing Regulation (EU) 2017/1344 of 18 July 2017⁵⁶⁸ amending Annex I to Council Regulation (EEC) No 2658/87 on the Common Customs Tariff and Commission Implementing Regulation (EU) 2017/1409 of 1 August 2017⁵⁶⁹ amending Implementing Regulation (EU) No 75/2013 and Regulation (EC) No 951/2006 on import duties in the sugar sector give details of the calculation of the sucrose content of various products including isoglucose and certain syrups by HPLC or refractometry.

4.4 Food supplements

A useful summary by the Department of Health on legislation relating to the sale of food supplements is available.⁵⁷⁰

As part of the e-Library of Evidence for Nutrition Actions (eLENA)⁵⁷¹ in August 2017 the WHO published two sets of guidelines on fortification of foods with micronutrients (vitamins and minerals):

- 'Use of multiple micronutrient powders for point-of-use fortification of foods consumed by pregnant women',⁵⁷²
- 'Use of Multiple Micronutrient Powders for Point-of-Use Fortification of Foods Consumed by Infants and Young Children Aged 6-23 Months and Children Aged 2-12 Years'.⁵⁷³

In a case referred from France the European Court (First Chamber) gave a ruling on 27 April 2017 that appears to block Member States from setting national legislation on vitamins and minerals in food supplements. The referring court, Tribunal de grande instance de Perpignan,

⁵⁶⁴ <https://www.gov.uk/government/publications/soft-drinks-industry-levy/soft-drinks-industry-levy>

⁵⁶⁵ http://www.britishsoftdrinks.com/write/MediaUploads/Publications/The_Economic_Impact_of_the_Soft_Drinks_Levy.pdf

⁵⁶⁶ <http://www.legislation.gov.uk/ukxi/2018/41/contents/made>

⁵⁶⁷ <http://www.legislation.gov.uk/ukxi/2018/264/contents/made>

⁵⁶⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.186.01.0003.01.ENG&toc=OJ:L:2017:186:TOC

⁵⁶⁹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.201.01.0021.01.ENG&toc=OJ:L:2017:201:TOC

⁵⁷⁰ <https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs>.

⁵⁷¹ <http://www.who.int/elena/en/>

⁵⁷² http://www.who.int/nutrition/publications/micronutrients/guidelines/mmpowders_pregnant_women/en/

⁵⁷³ http://www.who.int/elena/titles/guidance_summaries/micronutrientpowder_infants/en/

asked three questions in relation to Directive 2002/46/EC and Community principles of free movement of goods and mutual recognition.⁵⁷⁴ Do the above measures (1) prevent national legislation precluding mutual recognition of products lawfully marketed in another Member State where their nutrient content exceeds limits set in the national legislation, and allow (2) national legislation to set nutrient limits based on (3) national scientific opinions that derive multiples of recommended daily allowances? The Court decided⁵⁷⁵ that Member States cannot enact national legislation based on national scientific opinions to prohibit, by limits on nutrients, sale of food supplements lawfully manufactured or marketed in another Member State. Any upper safe nutrient levels must be established by a comprehensive scientific assessment of the risks for public health, based not on general or hypothetical considerations, but on relevant scientific data. It is for the referring court to assess whether the method for the setting of those amounts at issue in the main proceedings complies with those requirements.

Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 governs the addition of vitamins and minerals and of certain other substances to foods and Annex II to Directive 2002/46/EC establishes the list of vitamin and mineral substances, which may be used in the manufacture of food supplements. Requests for the addition of organic silicon as a source of silicon, and separately, for calcium phosphoryl oligosaccharides (POs-Ca®) as a source of calcium, to the list set out in Annex II to Directive 2002/46/EC were processed by the Commission with EFSA being consulted. A favourable EFSA opinion ensued on organic silicon (monomethylsilanetriol; MMST) as a novel food ingredient for use as a source of silicon in food supplements and bioavailability of orthosilicic acid from the source. It follows from that opinion that the use of organic silicon (monomethylsilanetriol) in food supplements is not of a safety concern as a source of silicon, provided that certain conditions are respected. In EFSA's opinion the addition of calcium phosphoryl oligosaccharides (POs-Ca®) to food and its use in food supplements is not of a safety concern as a source of calcium, provided that certain conditions are respected. Thus Commission Regulation (EU) 2017/1203 of 5 July 2017 added both to Annex II to Directive 2002/46/EC.⁵⁷⁶

4.5 Novel foods in supplements

See the July – September 2017 edition⁵⁷⁷ (Sections 4.1.1 and 4.4.2) of this report for details of the authorisation of L-ergothioneine and prolyl oligopeptidase as novel foods in food supplements.

4.5.1 Taxifolin

Commission Implementing Decision (EU) 2017/2079 of 10 November 2017⁵⁷⁸ authorised the placing on the market of taxifolin-rich extract from the wood of Dahurian Larch (*Larix gmelinii* (Rupr.) Rupr) as a novel food ingredient under Regulation (EC) No 258/97. Taxifolin is a flavonoid also known as dihydroquercetin,⁵⁷⁹ and was assessed by EFSA⁵⁸⁰ and is said to exhibit varied bioactivity. The taxifolin-rich extract is permitted in food supplements as defined in Directive 2002/46/EC, *excluding* food supplements for infants, young children, children and adolescents younger than 14 years, to maximum use level of 100 mg per day.

⁵⁷⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.090.01.0008.01.ENG&toc=OJ:C:2016:090:TOC

⁵⁷⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.202.01.0005.01.ENG&toc=OJ:C:2017:202:TOC

⁵⁷⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.173.01.0009.01.ENG&toc=OJ:L:2017:173:TOC

⁵⁷⁷ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-july-to-september-2017>

⁵⁷⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.295.01.0081.01.ENG&toc=OJ:L:2017:295:TOC

⁵⁷⁹ <https://pubchem.ncbi.nlm.nih.gov/compound/taxifolin#section=Top>

⁵⁸⁰ <https://www.efsa.europa.eu/en/efsajournal/pub/4682>

Commission Implementing Regulation (EU) 2018/461 of 20 March 2018⁵⁸¹ extended the use of taxifolin-rich extract as a novel food ingredient in milk products for the general population.

4.5.2 *Calanus finmarchicus* oil

Commission Implementing Decision (EU) 2017/2353 of 14 December 2017 authorised the placing on the market of oil from *Calanus finmarchicus* as a novel food ingredient under Regulation 258/97 (notified under document C(2017) 8426). The crustacean (marine zooplankton) *C. finmarchicus* is harvested in the Norwegian Economic Zone including Jan Mayen island. A specification including 'wax esters > 85%', minima for certain fatty acids and a maximum for peroxide value is given and the oil can be used in food supplements to a maximum consumption of 2.3 grams per day.⁵⁸²

4.5.3 Herbal roots

Commission Implementing Regulation (EU) 2018/469 of 21 March 2018⁵⁸³ authorised the placing on the market of an extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) as a novel food under Regulation 2015/2283. An EFSA report gives further information⁵⁸⁴ including that the product is a spray dried hot water extract and the three main families of compounds present are coumarins, iridoids and phenols. The product is a traditional Korean preparation with a target population of post-menopausal women for the purpose of providing relief from the symptoms of menopause. Further information on the toxicology, specification and analytical methods for the marker compounds are available in the Regulation itself and the EFSA report.

4.6 Obesity and healthy eating

Obesity, as well as causing obvious physical changes, can lead to a number of serious and potentially life-threatening conditions, such as type 2 diabetes, coronary heart disease, some types of cancer, such as breast cancer and bowel cancer, and stroke. Obesity can also affect quality of life and lead to psychological problems, such as depression and low self-esteem.⁵⁸⁵ There are major implications for the National Health Service.

The Department of Health maintains a section of the government website dedicated to obesity and healthy eating policy, and best practice papers.⁵⁸⁶

In Wales the Public Health (Wales) Act 2017, Deddf Iechyd y Cyhoedd (Cymru) 2017, received Royal assent in July 2017 and includes provision for a national strategy on tackling obesity and other public health matters such as smoking.⁵⁸⁷

⁵⁸¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.078.01.0007.01.ENG&toc=OJ:L:2018:078:TOC

⁵⁸² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.336.01.0045.01.ENG&toc=OJ:L:2017:336:TOC

⁵⁸³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.079.01.0011.01.ENG&toc=OJ:L:2018:079:TOC#ntc4-L_2018079EN.01001101-E0004

⁵⁸⁴ EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), Turck *et al.*, 2016 doi:10.2903/j.efsa.2016.4589, <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2016.4589>

⁵⁸⁵ <http://www.nhs.uk/Conditions/Obesity/Pages/Introduction.aspx>

⁵⁸⁶ <https://www.gov.uk/government/policies/obesity-and-healthy-eating>

⁵⁸⁷ <http://www.legislation.gov.uk/anaw/2017/2/part/1/enacted>

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 1990,⁵⁸⁸ the Food Standards Act 1999⁵⁸⁹ and the Official Feed and Food Controls (England) Regulations 2009 last amended, in England, by the Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015 that came into force on 6 April 2015, see Sections 5.4 and 6.1. European measures include Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law ... (etc),⁵⁹⁰ and Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities^{591, 592} which replaced Regulation (EC) No 882/2004⁵⁹³ in 2017. Background to this was given in a previous edition of this report.⁵⁹⁴ A fuller discussion of Regulation (EU) 2017/625 is at Section 1.4 of our April – June 2017 report.⁵⁹⁵

A dedicated section of the FSA website covers topics in enforcement and regulation. As well as information on food safety legislation, this section aims to provide enforcement officers with the tools they need to ensure that food safety and legal requirements are maintained and monitored in their area.⁵⁹⁶

The Food and Feed (Miscellaneous Amendments and Revocations) (Wales) Regulations 2018⁵⁹⁷ were made on 2 July 2018, and in force on 26 July 2018 to amend 27 statutory instruments and revoke a further 62. Among the changes, the Food Hygiene (Wales) Regulations 2006 are amended so that Regulation (EC) 852/2004 on the hygiene of foodstuffs is read with Commission Regulation (EU) No 2017/2158 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food. Regulation 25 amends the Fruit Juices and Fruit Nectars (Wales) Regulations 2013 (S.I. 2013/2750 (W. 267)) to implement Commission Delegated Regulation (EU) No 1040/2014 amending Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption to adapt its Annex I to technical progress. This allows plant proteins from wheat, peas and potatoes to be used for the clarification of products to which the Fruit Juices and Fruit Nectars (Wales) Regulations 2013 apply. These Regulations make other miscellaneous minor amendments to the legislation in the list below amending out of date references to domestic legislation and to EU instruments as follows:

- The Food (Lot Marking) Regulations 1996
- The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997
- The Bread and Flour Regulations 1998

⁵⁸⁸ <http://www.legislation.gov.uk/ukpga/1990/16/contents> and see also
[The Food Safety Act 1990 \(Consequential Modifications\) \(Scotland\) Order 1990](#)
[The Food Safety Act 1990 \(Consequential Modifications\) \(No 2\) \(Great Britain\) Order 1990](#)
[The Food Safety Act 1990 \(Consequential Modifications\) \(England and Wales\) Order 1990](#)
[The Food Safety Act 1990 \(Commencement No. 1\) Order 1990](#)
[The Food Safety Act 1990 \(Commencement No. 2\) Order 1990](#)
[The Food Safety Act 1990 \(Commencement No. 2\) Order 1990](#)

⁵⁸⁹ <http://www.legislation.gov.uk/ukpga/1999/28/contents>

⁵⁹⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1488723013503&uri=CELEX:02002R0178-20140630>

⁵⁹¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.095.01.0001.01.ENG&toc=OJ:L:2017:095:TOC

⁵⁹² <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1505320836050&uri=CELEX:02017R0625-20170407>

⁵⁹³ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1488722763430&uri=CELEX:02004R0882-20170216>

⁵⁹⁴ Walker M. J. (2017), Food and Feed Law: legislation review, January – March 2017, Section 5, pp 45 – 48,

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

⁵⁹⁵ <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2017>

⁵⁹⁶ <https://www.food.gov.uk/about-us/local-authorities>

⁵⁹⁷ <http://www.legislation.gov.uk/wsi/2018/806/contents/made>

- The Medical Food (Wales) Regulations 2000
- The Coffee Extracts and Chicory Extracts (Wales) Regulations 2001
- The Cocoa and Chocolate Products (Wales) Regulations 2003
- The Specified Sugar Products (Wales) Regulations 2003
- The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Wales) Regulations 2004
- The Genetically Modified Food (Wales) Regulations 2004
- The Food Hygiene (Wales) Regulations 2006
- The Official Controls (Animals, Feed and Food) (Wales) Regulations 2007
- The Addition of Vitamins, Minerals and Other Substances (Wales) Regulations 2007
- The Fishery Products (Official Controls Charges) (Wales) Regulations 2007
- The Quick-frozen Foodstuffs (Wales) Regulations 2007
- The Specified Products from China (Restriction on First Placing on the Market) (Wales) Regulations 2008
- The Products of Animal Origin (Disease Control) (Wales) Regulations 2008
- The Official Feed and Food Controls (Wales) Regulations 2009
- The Meat (Official Controls Charges) (Wales) Regulations 2009
- The Food Irradiation (Wales) Regulations 2009
- The Plastic Kitchenware (Conditions on Imports from China) (Wales) Regulations 2011
- The Materials and Articles in Contact with Food (Wales) Regulations 2012
- The Contaminants in Food (Wales) Regulations 2013
- The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013
- The Fruit Juices and Fruit Nectars (Wales) Regulations 2013
- The Products Containing Meat etc. (Wales) Regulations 2014
- The Animal Feed (Composition, Marketing and Use) (Wales) Regulations 2016
- The Animal Feed (Hygiene, Sampling etc. and Enforcement) (Wales) Regulations 2016
-

Schedule 3 to the Regulations lists the revoked measures.⁵⁹⁸

Similarly the Environment, Food and Rural Affairs (Miscellaneous Amendments and Revocations) Regulations 2018⁵⁹⁹, which came mainly into operation on 17 September 2018, make technical amendments to a raft of measures some of which concern food. Regulation 37 amends the definition of “Blended Malt Scotch Whisky” in the Scotch Whisky Regulations 2009. Regulation 38 amends the Beef and Veal Labelling Regulations 2010 to reflect provisions in Regulation (EU) No 653/2014 of the European Parliament and of the Council amending Regulation (EC) No 1760/2000 as regards electronic identification of bovine animals and labelling of beef. Regulation 55 makes a minor correction to the Transmissible Spongiform Encephalopathies (England) Regulations 2018. The Preserved Sardines (Marketing Standards) Regulations 1990 are updated with the relevant measures on trade descriptions for preserved sardines and sardine-type products. The Wine Regulations 2011 are amended to update with regard to the relevant EU regulations.

⁵⁹⁸ <http://www.legislation.gov.uk/wsi/2018/806/schedule/3/made>

⁵⁹⁹ <http://www.legislation.gov.uk/uksi/2018/942/contents/made>

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.⁶⁰⁰

The Intentional Adulteration Rule mandated by the FDA Food Safety Modernization Act (FSMA) requires food facilities, with some exceptions, to address hazards that may be introduced with the intention of causing wide-scale harm to public health. Further insights on protecting the food supply from intentional adulteration were given in December 2017 in an interview with FDA's Ryan Newkirk and Jon Woody.⁶⁰¹

A useful review of food safety policy and regulation in the United States is available (dated 2015) from the European Commission.⁶⁰²

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.⁶⁰³

Pursuant to 2017/C 205/08⁶⁰⁴ on networking of organisations operating in fields within EFSA responsibilities an updated list of competent organisations is available⁶⁰⁵ and includes, for the UK, Public Analyst laboratories, LGC, Fera, PHE and academic institutions.

5.2 Community Reference Laboratories

Regulation (EC) No 882/2004 lays down general rules for the performance of official controls to verify compliance with, *inter alia*, rules on food hygiene. In accordance with that Regulation, European Union reference laboratories ('EU reference laboratories') are responsible, in particular, for providing national reference laboratories with details of analytical methods and for the coordination of the application of such methods. The EU reference laboratories are listed in Annex VII to that Regulation (now replaced by Regulation 2017/625, see above).

Commission Regulation (EU) 2017/2460 of 30 October 2017⁶⁰⁶ amended Annex VII to Regulation (EC) No 882/2004 to remove reference to the EU reference laboratory on milk and milk products since its work (e.g. on methods of analysis for on quality markers such as somatic cells counts) was complete.

Commission Regulation (EU) 2018/192 of 8 February 2018⁶⁰⁷ amended Annex VII to Regulation 882/2004 on EU reference laboratories (EURLs) for contaminants in feed and food. The Joint Research Centre (JRC) of the European Commission hosted the EURL for heavy metals in feed and food, the EURL for polycyclic aromatic hydrocarbons (PAHs) and the EURL for mycotoxins in

⁶⁰⁰ <https://www.fda.gov/Food/GuidanceRegulation/FSMA/>

⁶⁰¹ A Conversation with Ryan Newkirk and Jon Woody <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm587803.htm>

⁶⁰² Directorate General For Internal Policies Policy Department A: Economic And Scientific Policy Food Safety Policy and Regulation In the United States, [http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU\(2015\)536324_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf)

⁶⁰³ <http://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/regulatory-initiatives/sfca/consultation/eng/1426531180176/1426531265317>

⁶⁰⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.205.01.0057.01.ENG&toc=OJ:C:2017:205:TOC

⁶⁰⁵ <http://www.efsa.europa.eu/sites/default/files/assets/art36listg.pdf>

⁶⁰⁶ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.348.01.0034.01.ENG&toc=OJ:L:2017:348:TOC

⁶⁰⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.036.01.0015.01.ENG&toc=OJ:L:2018:036:TOC

feed and food from 2006 to 1 January 2018. Following a 2017 call for applications to select and designate EURLs in the above areas, Part I of Annex VII to Regulation (EC) No 882/2004 was amended as follows:

Point 18: The EURL for metals and nitrogenous compounds in feed and food is the National Food Institute, Technical University of Denmark, Copenhagen.

Point 19: The EURL for mycotoxins and plant toxins in feed and food is RIKILT (Stichting Wageningen Research), Wageningen, The Netherlands.

Point 20: The EURL for process contaminants is the National Food Institute, Technical University of Denmark, Copenhagen.

Point 21: The EURL for halogenated persistent organic pollutants (POPs) in feed and food is the Chemisches und Veterinäruntersuchungsamt (CVUA) Freiburg, Germany.

Commission Implementing Regulation (EU) 2018/329 of 5 March 2018 designated a consortium led by Wageningen Livestock Research, The Netherlands, as European Union Reference Centre for Animal Welfare.⁶⁰⁸

See also Section 6.4, 'Feed Additives'.

5.3 Expert Scientific Committees

Following the March 2016 FSA triennial review of six FSA Scientific Advisory Committees the General Advisory Committee on Science (GACS) was replaced by the FSA Science Council chaired by Professor Sandy Thomas. The Science Council provides high-level, expert strategic insight, challenge and advice to the FSA's Chief Scientific Adviser and to the Board and executive of the FSA on the FSA's use of science to deliver FSA objectives. Its purpose is to help to ensure that the FSA identifies, sources, integrates and uses the best scientific evidence and expertise from all relevant disciplines to inform and evaluate its work. FSA defines science in a broad and inclusive way, including the natural, physical, social and economic, digital and data sciences.⁶⁰⁹

Other expert committees advising government on food and feed matters include:

- The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)⁶¹⁰
- The Advisory Committee on the Microbiological Safety of Food (ACMSF)⁶¹¹
- The Advisory Committee on Animal Feedingstuffs (ACAF)⁶¹²
- The Advisory Committee on Novel Foods and Processes (ACNFP),⁶¹³ and
- The Social Science Research Committee (SSRC).⁶¹⁴

The triennial review also recommended that the FSA should consult on moving the functions of the ACNFP and ACAF into a new committee, with a wider remit on innovation in the food chain. This was to be established by December 2017 but has not developed further to our knowledge. The review reinforced the importance of ensuring that the advisory committees continue to operate to the established high standards of independence, openness and transparency,

⁶⁰⁸ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.063.01.0013.01.ENG&toc=OJ:L:2018:063:TOC

⁶⁰⁹ <https://science-council.food.gov.uk/>

⁶¹⁰ <https://cot.food.gov.uk/>

⁶¹¹ <https://acmsf.food.gov.uk/>

⁶¹² <https://acaf.food.gov.uk/>

⁶¹³ <https://acnfp.food.gov.uk/>

⁶¹⁴ <https://ssrc.food.gov.uk/>

including holding open meetings and publishing papers, minutes and reports, and having access to FSA officials and the Board.

5.4 Food Law Code of Practice

The Food Law statutory Codes of Practice for England and Wales and separately for Scotland and Northern Ireland are available on the FSA website.⁶¹⁵ 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.⁶¹⁶ The Scottish Food and Feed Law Guide was published in December 2016.⁶¹⁷

A revised Food Law Code of Practice for England was issued on 30 March 2017.⁶¹⁸

5.5 Food law prosecutions database

In November 2015 the FSA announced the publication of a food law prosecutions database containing information supplied on a voluntary basis by local authority officers. At the time of writing (July 2018) the new FSA website no longer contained a reference or link to such data.

5.6 Food law enforcement

5.6.1 Primary Authorities

Primary Authority is a scheme that allows businesses to form partnerships with local authorities in order to receive advice and guidance on regulatory matters. The Co-ordination of Regulatory Enforcement Regulations 2017⁶¹⁹ made by the Department for Business, Energy & Industrial Strategy under powers in the Regulatory Enforcement and Sanctions Act 2008 create the framework under which Primary Authority operates. The regulations, brought into force on 1 October 2017, specify the regulators that may provide support to primary authorities⁶²⁰ and specify the functions in relation to which that support may be provided. The regulations describe what is regarded as enforcement action for the purposes of Primary Authority and the circumstances in which the enforcing authority does not have to notify the primary authority before it takes enforcement action. In such circumstances the enforcing authority must notify the primary authority as soon as it reasonably can after taking the enforcement action. There are procedures for references to the (BEIS) Secretary of State where there is dispute between the parties in relation to whether or not an enforcement action should go ahead.

For further information see the Regulatory Delivery section of the Department for Business, Energy & Industrial Strategy website.⁶²¹

⁶¹⁵ <https://www.food.gov.uk/enforcement/codes-of-practice/food-law-code-of-practice-2015>

⁶¹⁶ <https://www.food.gov.uk/about-us/food-and-feed-codes-of-practice>

⁶¹⁷ <http://www.foodstandards.gov.scot/scottish-food-and-feed-law-guide>

⁶¹⁸ https://signin.riams.org/files/display_inline/45497/Food-Law-CoP-Eng-01032017.pdf

⁶¹⁹ <http://www.legislation.gov.uk/ukxi/2017/835/contents/made>

⁶²⁰ The Competition and Markets Authority, The Food Standards Agency, The Gambling Commission, The Health and Safety Executive and the (BEIS) Secretary of State

⁶²¹ <https://www.gov.uk/government/organisations/regulatory-delivery>

5.7 Food Standards Scotland

The Food (Scotland) Act 2015⁶²² established the FSS and describes the structure and function of this new food body in Scotland which came into operation on 1 April 2015. See also Section 5.4, the Scottish Food and Feed Law Guide.

5.8 Import controls (contaminants, pesticides etc.)

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

Commission Implementing Regulation (EU) 2017/2298 of 12 December 2017 amended Regulation (EC) No 669/2009. Highly perishable products or the product packaging may mean that sampling at the point of entry would inevitably result in a serious risk to food safety or in the product being damaged to an unacceptable extent. There is thus a derogation to allow sampling at the place of destination. The amendment clarifies that the derogation may apply to imported products already listed in the Annex to Regulation 669/2009 as well as newly listed items.⁶²³

In July 2018 Commission Implementing Regulation (EU) 2018/941⁶²⁴ amended Regulation (EC) No 669/2009. In particular, newly included were consignments of goji berries from China for pesticides residues and of turnips prepared or preserved by vinegar or acetic acid ('pickled turnips') from Lebanon and from Syria for Rhodamine B. Several entries in the list were deleted freeing them from enhanced import controls. These were *Brassica oleracea* from China, strawberries from Egypt, dried grapes from Iran, peas with pods from Kenya, yardlong beans from Thailand and aubergines and Ethiopian eggplant from Uganda. For other entries (pineapples from Benin and lemons and pomegranates from Turkey) a decrease in the frequency of controls for pesticides residues was allowed. Consignments of okra (food, fresh and frozen) from India were subject to conditions (a health certificate and the results of the sampling and analysis for pesticides residues) which decreased pesticides incidence rendered no longer appropriate. However in the absence of these conditions an increased level of official controls at Union borders is required. The existing entries on tea from China in the list required testing for the herbicide triflurarin. This is no longer required owing to reduced incidence, but is replaced with a requirement for testing for the insecticide tolfenpyrad. Other administrative amendments were made.

See also Section 2.15, Food hygiene, for details of temporarily suspended imports from Bangladesh of Betel leaves due to the presence of a wide range of *Salmonella* strains.

Implementing Regulation (EU) No 884/2014⁶²⁵ remains in force and imposes special conditions on the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and was last amended by Regulation (EU) 2016/2106 that requires health certificates to accompany imports of spices from Ethiopia, groundnuts from Argentina, hazelnuts from Azerbaijan, dried figs and hazelnuts from Turkey and groundnuts from India.⁶²⁶

⁶²² http://www.legislation.gov.uk/asp/2015/1/pdfs/asp_20150001_en.pdf

⁶²³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.329.01.0026.01.ENG&toc=OJ:L:2017:329:TOC#ntr15-L_2017329EN.01002802-E0015

⁶²⁴ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.166.01.0007.01.ENG&toc=OJ:L:2018:166:TOC

⁶²⁵ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1499096567716&uri=CELEX:02014R0884-20161222>

⁶²⁶ 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

Commission Implementing Regulation (EU) 2015/949 approves the pre-export checks carried out on certain food or feed by certain third countries as regards the presence of certain mycotoxins. Such an approval of pre-export checks performed by the United States of America (US) authorities on aflatoxins in groundnuts was granted by the EU in 2008. The approval attests to the adequacy of pre-export controls so as to replace or reduce the documentary, identity and physical checks laid down in EU law. However, following an increase of non-compliance as regards the presence of aflatoxins in groundnuts from the US, groundnuts (peanuts) from the US were removed from the list of approved pre-export checks by Commission Implementing Regulation (EU) 2017/1269 of 13 July 2017 amending Implementing Regulation 2015/949.⁶²⁷

5.9 Local authority enforcement activity

On 21 November 2016 the FSA published official statistics on food law enforcement by local authorities across the UK for the year 2015/16. The figures are said to show an increase in a number of areas of local authority enforcement activity, and levels of hygiene compliance in food business, in spite of reported staffing reductions.⁶²⁸

On 18 September 2017 the FSA published official statistics on food law enforcement by local authorities for the year 2016/17. The information provided by local authorities and compiled by the FSA, gives a detailed breakdown of enforcement activity across the UK. These new data show an increase in food hygiene compliance in food establishments, continuing the trend of increases since 2014/15. However there was a decrease in the number of planned interventions for food standards, which covers areas such as authenticity and food fraud. FSA intends to use the data, along with other intelligence, to identify and target underperforming local authorities and work with them to secure improvements.⁶²⁹

We remain open to including in this review any updates communicated by individual local authorities to the author. However see Section 5.5 for the food law prosecutions database which is based on local authority activity.

5.10 Multi-Annual National Control Plan

The FSA has published its annual report on progress towards implementation of the UK Multi-Annual National Control Plan (MANCP). The FSA considered that the report, which is based on data collected for 2016, shows that overall level of compliance in all sectors in the UK was satisfactory when assessed against expectations.⁶³⁰

5.11 National sampling priorities for food surveillance

The FSA worked with UK local authorities from 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. On 29 November 2016 the FSA held a 'Food Surveillance Summit' as part of the

⁶²⁷ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.183.01.0009.01.ENG&toc=OJ:L:2017:183:TOC

⁶²⁸ <http://webarchive.nationalarchives.gov.uk/20171207155526/https://www.food.gov.uk/news-updates/news/2016/15747/fsa-publishes-la-food-law-enforcement-information>

⁶²⁹ <http://webarchive.nationalarchives.gov.uk/20171207154432/https://www.food.gov.uk/news-updates/news/2017/16528/fsa-publishes-local-authority-food-law-enforcement-information>

⁶³⁰ <http://webarchive.nationalarchives.gov.uk/20171207153819/https://www.food.gov.uk/news-updates/news/2017/16505/2016-annual-report-on-uk-multi-annual-national-control-plan-published>

development phase for a new food surveillance approach.⁶³¹ We are unaware of any further support going forward.

5.12 Online sales and surveillance

Online sales of food and general products is increasing and presents particular problems for regulators and enforcement authorities, mainly around the ephemeral nature of non-compliant operations, provision of information, lack of a physical premises to inspect, and jurisdictional issues. The Food Safety Authority of Ireland, FSAI, have issued what appears to be the first guidance setting out the information that must be provided to consumers by food businesses promoting or selling food online via websites or social media. It specifies what a business must do to comply with the law to ensure that consumers get the same information online, before making a purchase, as they would if they bought the product in a store. The legislation around labelling, advertising, health claims, nutrition claims and allergen declarations apply to foods sold online, as well as over the counter.⁶³² The European Commission have issued guidance on market surveillance of non-food products sold online that may, by analogy, assist those seeking to police online food sales.⁶³³

5.13 Regulators' development needs analysis, RDNA

The food section of the RDNA self-assessment tool has been updated to include the competency statements for authorised officers and lead food officers in the Food Law Code of Practice 2015.⁶³⁴ RDNA appears to be a useful mechanism of clarifying regulatory need and seems to be open to all stakeholders.⁶³⁵ 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.⁶³⁶

5.14 Standards in Public Life

The Committee on Standards in Public Life presented in September 2016 a report on how regulatory bodies in the United Kingdom uphold the Seven Principles of Public Life. The Committee was struck by the complexity and disparity of the regulatory landscape with a shared need to maintain integrity through independence – both from government and those they regulate – avoiding undue influence and ensuring the decisions they make are fair, well-reasoned and evidence-based. In light of the result of the June 2016 referendum in which the British people voted to leave the European Union (EU), the UK's regulatory landscape is likely to be substantially restructured in the coming years. The Committee made recommendations on Governance, Codes of Conduct, staff 'revolving door' issues, independence, transparency and external leadership.⁶³⁷

⁶³¹ <http://webarchive.nationalarchives.gov.uk/20171207155420/https://www.food.gov.uk/news-updates/news/2016/15753/food-surveillance-summit-get-involved>

⁶³² https://www.fsai.ie/news_centre/press_releases/selling_online_guide_20072017.html

⁶³³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.250.01.0001.01.ENG&toc=OJ:C:2017:250:TOC

⁶³⁴ https://www.gov.uk/government/news/fresh-food?mc_cid=127fb196ca&mc_eid=f1b5809dbc

⁶³⁵ <http://rdna-tool.bis.gov.uk/>

⁶³⁶ <http://www.regulatorsdevelopment.info/grip/food>

⁶³⁷ 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

5.15 Statutory duties

Pursuant *inter alia* to Local Authority statutory duties Judicial Reviews of a local authority decision to make significant cuts to the library service in Northamptonshire were decided by Mrs Justice Yip sitting in the High Court (Queen's Bench Division, Administrative Court).⁶³⁸ The statutory duty concerned is in the Public Libraries and Museums Act 1964⁶³⁹ which broadly defines 'library authority' as a local authority function and, in Section 7, provides for a general duty ... of every library authority to provide a comprehensive and efficient library service Yip, J. held that important decisions needed to be taken by the Defendant local authority, having regard to the core duty under s.7 of the 1964 Act and other statutory duties. When taking decisions that would impact on the library provision, the Cabinet and the full Council needed to be properly informed as to the decisions required, the legal framework and all relevant considerations. Without making any decisions about the merits of any proposed library closures, which remains a matter for the Local Authority, Yip, J. quashed certain decisions as to closures. The Judgement, hinging as it does on the circumstances of the claimants and the decision trail of the local authority may or may not have any bearing on other statutory duties.

5.16 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 2074/2005⁶⁴⁰ of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 (hygiene rules for food of animal origin, (EC) No 854/2004 (official controls on products of animal origin intended for human consumption) and Regulation (EC) No 882/2004 (Official Controls). The requirements of Regulation 2074/2005 include methods and limit values for total volatile basic nitrogen (TVB-N) in fish, methods for marine biotoxins, and for raw milk and heat-treated milk, the applicable official controls for the inspection of meat, provisions on water retention agents in poultry and the calcium content of mechanically separated meat.

5.17 Corporate Reports

The Annual Report and Westminster Accounts 2016/17 and the Annual Report and Consolidated Accounts 2016/17⁶⁴¹ of the FSA were published in July 2017.

5.18 Laboratory accreditation

ISO/IEC 17025 'General requirements for the competence of testing and calibration laboratories' – the main ISO standard used by testing and calibration laboratories – was re-issued at the end of November 2017. The United Kingdom Accreditation Service ([UKAS](https://www.ukas.com)) and UKAS accredited laboratories must transfer laboratory accreditation from ISO/IEC 17025:2005 to ISO/IEC 17025:2017 by the internationally agreed deadline of 1 December 2020 (3 years after publication). Any accreditation to the 2005 version will cease to be valid after this date.⁶⁴²

⁶³⁸ The Queen (on the application of WX), and of John Connolly), Claimants, and Northamptonshire County Council, Defendant, <https://www.bailii.org/ew/cases/EWHC/Admin/2018/2178.html>

⁶³⁹ <https://www.legislation.gov.uk/ukpga/1964/75/contents>

⁶⁴⁰ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1494594527755&uri=CELEX:02005R2074-20160603>

⁶⁴¹ <https://www.food.gov.uk/about-us/reports-and-accounts>

⁶⁴² <http://ukas.newsweaver.com/update/j6mzqsyzt21cexiztd9h3?email=true&a=11&p=53144317>

5.19 Better training for safer food' programme

Commission Implementing Decision of 17 May 2018 (2018/C 171/02) set out the financing of the 2018 work programme on training in the field of food and feed safety, animal health, animal welfare and plant health in the framework of the 'Better training for safer food' programme. The maximum contribution for the implementation of the work programme for the year 2018 is set at €17,500,000.⁶⁴³

6 Feeding stuffs and fertilisers

6.1 Feeding stuffs

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

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

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

The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015⁶⁴⁴ (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;

⁶⁴³ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2018.171.01.0002.01.ENG&toc=OJ:C:2018:171:TOC
⁶⁴⁴ http://www.legislation.gov.uk/ukxi/2015/255/pdfs/ukxi_20150255_en.pdf

- 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 2016⁶⁴⁵ (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) 2016⁶⁴⁶ (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).

The Animal Feed (Basic Safety Standards) (...*) Regulations 2018 were made in *Scotland,⁶⁴⁷ *Wales⁶⁴⁸ and *Northern Ireland⁶⁴⁹ in January 2018. Each set of regulations transpose in their respective countries in relation to animal feed, Article 21 of Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. They provide that a person must not deliberately add a radioactive substance in the production of feed, and must not import or export any animal feed to which a radioactive substance has been intentionally added during production. The regulations set out the offence of failing to comply, punishable on conviction by a fine or imprisonment not exceeding 3 months with potential defences (fault of another person, mistake or reliance on information supplied by another person ...) and the means of relying on them. These regulations are designated as “relevant feed law” for the purposes of the Official Feed and Food Controls (Scotland) Regulations 2009, “specified feed law” for the purposes of the Animal Feed (Hygiene, Sampling etc. and Enforcement) (Wales) Regulations 2016 and the Animal Feed (Hygiene, Sampling etc. and Enforcement) Regulations (Northern Ireland) 2016.

Provisions are also made so that, among other things, authorised officers may serve improvement notices for failure to comply with the regulations.

⁶⁴⁵ http://www.legislation.gov.uk/nisr/2016/4/pdfs/nisr_20160004_en.pdf

⁶⁴⁶ http://www.legislation.gov.uk/nisr/2016/5/pdfs/nisr_20160005_en.pdf

⁶⁴⁷ <http://www.legislation.gov.uk/ssi/2018/15/contents/made>

⁶⁴⁸ <http://www.legislation.gov.uk/wsi/2018/40/contents/made>

⁶⁴⁹ <http://www.legislation.gov.uk/nisr/2018/16/contents/made>

The accompanying policy documents note the consultation on the regulations received few responses, including one from the Government Chemist that raised specific and technical concerns on the possibility of naturally occurring potassium and polonium radioactivity in feed and also the general use of security devices applied to feed. The policy documents note these specific points will be more appropriately addressed by way of guidance in the future.

Commission Regulation (EU) 2017/2229 of 4 December 2017⁶⁵⁰ amended Annex I to Directive 2002/32/EC on undesirable substances in animal feed as regards maximum levels for lead, mercury, melamine and deoquinatone.

Commission Regulation (EU) 2017/2279 of 11 December 2017 amended certain Annexes to Regulation (EC) No 767/2009 on the placing on the market and use of feed. Annex II was amended to include specific expressions for feed for pets, including in English “pet food”. Annex IV Part A on tolerances for analytical constituents and feed additives in feed materials and compound feed is replaced. Annexes VI, and VII on labelling particulars for feed materials and compound feed for food-producing and non-food producing animals are replaced. Annex VIII on specific provisions for the labelling of feed which does not comply with safety and marketing requirements is amended with labelling provisions for contaminated materials only to be used as feed after detoxification in approved establishments, and former foodstuffs that need to be processed before they can be used as feed, must be labelled as: “former food, only to be used as feed material after ... (designation of the adequate process...)”.⁶⁵¹

6.1.1 Mycotoxin recommended limits

Commission Recommendation (EU) 2016/1319⁶⁵² of 29 July 2016 amended Recommendation 2006/576/EC as regards deoxynivalenol, zearalenone and ochratoxin A in pet food. Commission Recommendation 2006/576/EC establishes guidance values for deoxynivalenol, zearalenone, ochratoxin A, fumonisins B1+B2 and T-2 and HT-2 toxin in feed materials and compound feed. The current guideline level for deoxynivalenol in feed for dogs of 5 mg kg⁻¹ (from recent evidence including from EFSA) appears too high and is reduced to 2 mg kg⁻¹. Guideline levels for zearalenone and ochratoxin A in feed for cats and dogs are established at 0.2 mg kg⁻¹ and 0.01 mg kg⁻¹ respectively.

6.1.2 Dioxin testing

Regulation (EC) No 183/2005 of the European Parliament and of the Council lays down general rules on feed hygiene and processing conditions, the latest consolidated version⁶⁵³ is that of 23 April 2016 and includes updates in previous editions of this legislation review.

Commission Regulation (EU) 2017/771 of 3 May 2017⁶⁵⁴ amended Regulation (EC) No 152/2009 (see Section 6.1) as regards the methods for the determination of the levels of dioxins and polychlorinated biphenyls. Regulation 152/2009 includes methods for the determination of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), dioxin-like polychlorinated biphenyls (PCBs) and non-dioxin-like PCBs in feed. On evidence from the EU reference laboratory for dioxins and PCBs in feed and food that analytical results for dioxins and

⁶⁵⁰ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.319.01.0006.01.ENG&toc=OJ:L:2017:319:TOC

⁶⁵¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.328.01.0003.01.ENG&toc=OJ:L:2017:328:TOC

⁶⁵² <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016H1319>

⁶⁵³ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1498138333211&uri=CELEX:02005R0183-20160423>

⁶⁵⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.115.01.0022.01.ENG&toc=OJ:L:2017:115:TOC

PCBs in certain cases are not reliable when the performance criteria provided for in Part B of Annex V to Regulation (EC) No 152/2009 are not applied by laboratories performing the analysis of samples taken by feed business operators in accordance with Regulation (EC) No 183/2005, the application of the performance criteria for the analysis of such samples was made obligatory. Regulation 2017/771 deletes the decision limit in Commission Decision 2002/657/EC for the analysis of dioxins, furans and PCBs in feed in favour of the expanded uncertainty using a coverage factor of 2, giving a level of confidence of approximately 95% and references guidance documents for the measurement uncertainty and for the estimation of the Limit of Detection (LOD) and Limit of Quantification (LOQ).⁶⁵⁵ Reporting requirements for physico-chemical methods used for screening are aligned with similar reporting requirements for bioanalytical screening methods and performance criteria are simplified and aligned generally. Along with some amended technical specifications, such as recoveries of isotope-labelled standards and other minor modifications, the whole Part B of Annex V to Regulation (EC) No 152/2009 is replaced.

6.1.3 Nickel in feed

EFSA requires further data on Ni in food of animal origin and accordingly Commission Recommendation (EU) 2016/1110 of 28 June 2016 asks Member States to monitor for the presence of nickel in feed.⁶⁵⁶

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.⁶⁵⁷

6.2 Feed use of food no longer intended for human consumption

Commission Notice 2018/C 133/02 gives 'Guidelines for the feed use of food no longer intended for human consumption'. The Commission established an action plan to reduce food waste. One of the initiatives is, without competing with food banks, to valorise the nutrients of food which is, for commercial reasons, problems of manufacturing or certain defects, no longer intended for human consumption. This can be done through its safe use in animal nutrition, without

⁶⁵⁵ http://ec.europa.eu/food/safety/animal-feed_en

⁶⁵⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1471533458929&uri=CELEX:32016H1110>

⁶⁵⁷ 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

compromising animal and public health. This avoids composting, transformation to biogas, incineration or landfilling. The distinction between food, animal by-products, feed and waste has evident implications with respect to the legislative framework. These guidelines intend to address these issues within the existing legal framework. Thus they do not create any new legal provisions, nor do they seek to cover all provisions in this area in an exhaustive manner. It should also be noted that they are without prejudice to the interpretation of Union law provided by the Court of Justice of the European Union.

The objective is to facilitate the feed use of certain food no longer intended for human consumption, with and without products of animal origin. The guidelines should assist the national and local competent authorities and the operators in the food chain in applying the relevant legislation. The scope covers products from the food manufacturing process (supplied by food producers), and food which has been placed on the market, packaged or in bulk (supplied by wholesalers and retailers of food). These guidelines do not address the feed use of food additives, food enzymes and food flavourings food supplements or catering waste.

6.3 Unlawful feedingstuffs (BSE)

See Section 2.12 for measures relation to 'unlawful feedingstuffs' under TSE regulations, (the feeding to ruminants of protein derived from animals is prohibited).

6.4 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.⁶⁵⁸ Guidance is available intended to help applicants in their preparation of technical dossiers for applications for authorisation.⁶⁵⁹

The Animal Feed (Scotland) Amendment Regulations 2017 No. 38,⁶⁶⁰ in force 23 March 2017, provide for the execution and enforcement of Commission Regulation (EU) 2015/327 amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions of use of additives consisting of preparations. These Regulations amend the Animal Feed (Scotland) Regulations 2010.

Commission Implementing Regulation (EU) 2017/1145 of 8 June 2017, pursuant to Article 10(5) of Regulation (EC) No 1831/2003, lists the repeal of obsolete provisions authorising feed additives which were entered in the Community Register of Feed Additives as existing products and for which no applications in accordance with Article 10(2) and (7) of Regulation (EC) No 1831/2003 were submitted before the deadline provided for in those provisions, or for which an application was submitted but subsequently withdrawn. The Annex to Regulation (EU) 2017/1145 lists over 200 such additives.⁶⁶¹

Commission Implementing Regulation (EU) 2018/353 of 9 March 2018⁶⁶² **corrected the above Implementing Regulation (EU) 2017/1145** in the following respects.

- a) The list of additives to be withdrawn mistakenly included the feed additive coccidiostat authorised by Commission Regulation (EC) No 1463/2004 [salinomycin sodium

⁶⁵⁸ http://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register/index_en.htm

⁶⁵⁹ <http://www.efsa.europa.eu/en/efsajournal/pub/4473>

⁶⁶⁰ <http://www.legislation.gov.uk/ssi/2017/38/contents/made>

⁶⁶¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.166.01.0001.01.ENG&toc=OJ:L:2017:166:TOC

⁶⁶² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.068.01.0003.01.ENG&toc=OJ:L:2018:068:TOC

product, Sacox 120 microGranulate] although an application was submitted in due time.

- b) Commission Regulation (EC) No 833/2005 was mentioned in recital 3 as to be amended and repealed whereas it is simply repealed.
- c) Commission Regulation (EC) No 1459/2005 was not repealed although it authorises certain iodine compounds that are to be withdrawn
- d) Commission Regulation (EC) No 1443/2006 was erroneously repealed Only Article 1 of and Annex I to that Regulation should be deleted as only those provisions concern certain enzymes that are to be withdrawn.
- e) The provisions of Commission Regulation (EC) No 1334/2003 authorising some iron compounds, to be withdrawn from the market were not deleted.
- f) In Part A of Annex I to Implementing Regulation (EU) 2017/1145 setting out the feed additives to be withdrawn for all species and categories of animals, in the table concerning vitamins, the L form of the vitamin menadione sodium bisulphite is included. No reference to this L form was made in the authorisation.
- g) Parts A and B of Annex I to Implementing Regulation (EU) 2017/1145 are corrected as regards some colourants as the species and categories of animals for which those colourants are required to be withdrawn from the market and the functions of those colourants were not indicated correctly. The requirement to withdraw the additive from the market for some of them applies only for certain species and the use as colourant is restricted to certain functions.

Feed additive authorisations are not routinely reported however the following non-authorisation may be of interest. Commission Implementing Regulation (EU) 2018/1254 of 19 September 2018 denied authorisation of riboflavin (80%) produced by *Bacillus subtilis* KCCM-10445 as a feed additive in the functional group of vitamins, pro-vitamins and chemically well-defined substances having similar effect. The additive is produced by a genetically modified strain and, based on information supplied by the applicant company, EFSA concluded that neither the production strain nor its recombinant DNA would be detected in the final product. However, a national competent authority laboratory, using a developed PCR assay detected the presence of viable cells and of rDNA from the production strain in some reference samples of the additive. Consequently, although the applicant contested the laboratory method, EFSA reviewed the newly emerged results and the Commission has denied the authorisation.⁶⁶³

6.4.1 Formaldehyde

Commission Implementing Regulation (EU) 2018/183⁶⁶⁴ of 7 February 2018 refusing authorisation of formaldehyde as a feed additive following applications for it is reported here owing to the general light it throws on this compound.

EFSA concluded in 2014 that formaldehyde would be safe at specific concentration levels for chickens for fattening, laying hens, Japanese quail and piglets (weaned) but that no safe level for all animal species and categories, including all poultry and pigs, could be determined and that formaldehyde raised concerns for the safety of the users. Formaldehyde is a toxic substance, a strong irritant, a potent skin and respiratory sensitiser (including occupational asthma) and causes eye damage. In its opinions, EFSA mentioned that, while local irritation is expected to strongly promote carcinogenesis, lower local concentrations of formaldehyde are known to produce DNA adducts and that therefore it was prudent not to consider the exposure to non-

⁶⁶³ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.237.01.0005.01.ENG&toc=OJ:L:2018:237:TOC

⁶⁶⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.034.01.0006.01.ENG&toc=OJ:L:2018:034:TOC

irritant concentration as totally risk-free. EFSA also concluded that on the basis of the present knowledge a causal association between formaldehyde exposure and leukaemia could not be ruled out. Therefore, EFSA recommended that measures should be taken to ensure that the respiratory tract, as well as the skin and eyes, of any person handling the product are not exposed to any dust, mist or vapour generated by the use of formaldehyde. In addition, EFSA recommended that consideration should be given to whether the strict protection measures, once established, would effectively protect users. EFSA also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

Formaldehyde is classified as carcinogenic (category 1B) by inhalation and germ cell mutagenic (category 2) under Regulation (EC) No 1272/2008 of the European Parliament and of the Council. In the framework of EU legislation on health and safety at work, occupational exposure limits are being developed for formaldehyde. Authorisation of an additive must take into account all the information available regarding the risks, including user or workers' handling of formaldehyde, and risks to animals or to consumers of the animal products concerned. On this basis, the authorisation of formaldehyde as a feed additive for use as preservative and hygiene condition enhancer was denied. Existing stocks of formaldehyde as an additive belonging to the additive category 'technological additives' and to the functional group 'preservatives' for use in skimmed milk for pigs up to the age of 6 months, and of premixtures containing that additive, must be withdrawn from the market as soon as possible and at the latest by 28 May 2018. Skimmed milk containing the additive or skimmed milk containing its premixtures and compound feed containing such skimmed milk, which have been produced before 28 May 2018 must be withdrawn from the market as soon as possible and at the latest by 28 August 2018.

6.4.2 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 2015/1761⁶⁶⁵ 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.

6.5 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 2003.⁶⁶⁶ This regulation is updated from time to time, including with references to validated analytical methods, see for example (non-exhaustively) Commission Regulation (EU) 2016/1618.⁶⁶⁷

⁶⁶⁵ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.257.01.0030.01.ENG

⁶⁶⁶ 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>

⁶⁶⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1618>

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