



# Food and feed law:

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

**July – September 2016**

**Government Chemist Programme Report**



Department for  
Business, Energy  
& Industrial Strategy

FUNDED BY BEIS



# **Food and feed law: A review of changes in food and feed legislation and associated activity affecting the UK**

## **July – September 2016**

Author: Michael Walker

Contact point: Michael Walker  
michael.walker@lgcgroup.com  
07738 179 985

Report no. LGC/R/2016/545

Approved by:



Dr Julian Braybrook

---

Date: 9 December 2016

Preparation of this report was funded by the Department for Business,  
Energy & Industrial Strategy.

© LGC Limited 2016

## Introduction to 'Food and feed law' review series

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

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

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

The categories are:

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

European measures are normally listed first, along with the implementing domestic legislation, followed by purely domestic legislation. English regulations are cited in the text; however for significant measures, where equivalent regulations have been made at the same time for Scotland, Wales and Northern Ireland, devolved references are given. Potentially temporary and local measures, such as prohibition legislation for shellfish harvesting areas, have not been recorded.

**Please note –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 2016 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.**

Hyperlinks in the document were accessed and available at the date of this report.

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

The sources of information used have been Office of Public Sector Information ([OPSI](#)), Food Standards Agency ([FSA](#)) updates, European Food Safety Authority ([EFSA](#)) and the European legislative information database, [EUR-Lex](#). Extensive use has been made of the explanatory notes that accompany each set of domestic regulations.

## Executive summary

This report provides an update on developments in food and feed law and related scientific and regulatory issues for the period from July to September 2016.

Emerging priorities reported in our previous quarterly report were updated from the deliberations of the Emerging Risks Exchange Network which included antimicrobial resistance, the circular economy – pollution from waste to fertiliser to the food chain – pyrrolizidine alkaloids, cyanobacteria toxins in food, tetrodotoxin, the risk profile of insects as food and feed, and cyanogenic glycosides in apricot kernels and products derived from apricot kernels.

In July 2016 the Food Standards Agency (FSA) published the continuing series of within year lists of incidents for the three month period, April to June 2016. As in previous quarterly reports allergy alerts were prominent.

Food hygiene rating schemes, displaying information based on local authority inspection of food premises to help consumers choose where to eat out obtained statutory force in Wales and Northern Ireland with penalties for failing to display the information. The food hygiene rating scheme in England and the Food Hygiene Information Scheme in Scotland remain voluntary.

Regulation (EC) No 1935/2004 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. A key subordinate measure, Regulation 10/2009 (The 'Food Contact Plastics' Regulation) was extensively amended in the quarter by Commission Regulation (EU) 2016/1416.

Three novel foods were approved in the quarter: UV-treated milk resulting in an increase in the vitamin D content of the milk; *trans*-resveratrol to be used in food supplements; and monomethylsilanetriol as a source of silicon. *Trans*-resveratrol, a compound found in grapes, has been investigated for its cardiovascular benefits however no valid health claim has been authorised to date. The novel food assessment relates to synthetic *trans*-resveratrol

Transmissible Spongiform Encephalopathies, TSE, are controlled under framework legislation, Regulation (EC) No 999/2001 which was amended in the quarter by Commission Regulation (EU) 2016/1396. 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, and various legislative and technical references were updated.

Domestic legislation to implement Regulation 609/2013 on infant and follow-on formula, food for medical purposes and food for weight control continued in the quarter.

Further new technical and legislative issues described in the main report include new approvals for GMOs, amendments to spirit drinks and health claims legislation, and new guideline limits for deoxynivalenol, zearalenone and ochratoxin A in pet food

We took the opportunity to add entries to the main report on the Biocidal Product Regulation (Regulation (EU) 528/2012), herbal medicines and fertilisers.

# Contents

- 1 Cross-cutting issues..... 6
  - 1.1 Emerging risks ..... 6
    - 1.1.1 National Food Crime Unit..... 7
    - 1.1.2 Incidents ..... 7
  - 1.2 Information management..... 8
- 2 Food safety..... 9
  - 2.1 Food hypersensitivity ..... 9
  - 2.2 Contaminants ..... 10
    - 2.2.1 Sampling and analysis for contaminants..... 10
    - 2.2.2 Mycotoxins..... 10
    - 2.2.3 Dioxins and PCBs..... 10
  - 2.3 Non regulated contaminants ..... 11
    - 2.3.1 Acrylamide..... 11
    - 2.3.2 Apricot kernels – cyanide ..... 11
    - 2.3.3 Glycerol based process contaminants (MCPD and GE)..... 12
    - 2.3.4 Endocrine disruptors..... 12
    - 2.3.5 Nickel ..... 12
  - 2.4 Food additives ..... 13
    - 2.4.1 Sulphites ..... 14
    - 2.4.2 Additives in wine ..... 14
    - 2.4.3 Flavourings ..... 14
  - 2.5 Food contact materials..... 15
  - 2.6 Marine biotoxins ..... 15
  - 2.7 Pesticides ..... 15
    - 2.7.1 Biocidal Products..... 16
  - 2.8 Products of animal origin ..... 16
  - 2.9 Radioactivity ..... 17
  - 2.10 Transmissible spongiform encephalopathies ..... 17
  - 2.11 Veterinary residues ..... 17
  - 2.12 Food Hygiene..... 18
    - 2.12.1 Food hygiene rating schemes ..... 19
  - 2.13 Water for human consumption..... 19
  - 2.14 Psychoactive substances..... 21
  - 2.15 Herbal products and medicines ..... 23
- 3 Consumer choice ..... 24
  - 3.1 Food labelling..... 24
    - 3.1.1 Country of origin labelling..... 24

3.1.2	Meat products.....	25
3.1.3	Fish labelling.....	25
3.1.4	Defra food labelling guidance.....	25
3.1.5	Organic food.....	25
3.1.6	Net Quantities.....	26
3.2	Food fraud/food crime.....	26
3.3	Genetically modified organisms.....	27
3.3.1	Cultivation of GMOs.....	27
3.4	Cloned animals.....	28
3.5	Honey.....	28
3.6	Novel foods.....	29
3.7	Olive oil.....	30
3.8	Protected names.....	30
3.9	Consumer attitudes.....	31
3.10	Spirit drinks etc.....	31
3.11	The Consumer Rights Act 2015.....	31
3.12	International Standards for Fruit and Vegetables.....	31
4	Health and nutrition.....	32
4.1	Nutrition and health claims.....	32
4.2	Food for infants & young children, medical purposes and weight control.....	33
4.3	Sugar.....	34
4.4	Food supplements.....	35
5	Regulation.....	35
5.1	Regulators' development needs analysis, RDNA.....	35
5.2	Food law prosecutions database.....	36
5.3	Food Standards Scotland.....	36
5.4	Import controls.....	36
5.5	Local authority enforcement activity.....	37
5.6	Multi-Annual National Control Plan.....	37
5.7	Food Law Code of Practice.....	37
5.8	National sampling priorities for food.....	37
5.9	Community Reference Laboratories.....	37
6	Feeding stuffs and fertilisers.....	37
6.1	Feeding stuffs.....	37
6.1.1	Mycotoxin recommended limits.....	39
6.1.2	Dioxin testing.....	39
6.1.3	Nickel in feed.....	40
6.2	Feed additives.....	40

6.2.1	Community and National Reference Laboratories .....	40
6.3	Fertilisers .....	40

# 1 Cross-cutting issues

## 1.1 Emerging risks

The Emerging Risks Exchange Network, EREN, has been referred to in previous reports<sup>1</sup> and regularly updates outline emerging risks in brief meeting reports<sup>2</sup>. At the last meeting of EREN (April 2016) the following chemical risks were discussed:

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

One of the European Food Standards Agency's (EFSA) key aims is to develop, in collaboration with Member States, an assessment of "prioritised activities and initiatives which are likely to have the greatest impact in strengthening risk assessment and risk monitoring". To support this, EFSA commissioned a 'Delphi'<sup>3</sup> survey of risk assessment experts throughout Europe.<sup>4</sup> Analysis of the initial results yielded consensus with 28 topics taken forward for further discussion with the experts. The 28 topics were as follows and the top-rated **highlighted in bold**:

### Generic:

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

### Chemical:

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

---

<sup>1</sup> <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-january-to-march-2016>

<sup>2</sup> <https://www.efsa.europa.eu/en/topics/topic/emergingrisks>

<sup>3</sup> The Delphi technique is a structured process that uses a series of questionnaires or 'rounds' to gather information. Rounds are held until group consensus is reached, see for example Boulkedid, R., Abdoul, H., Loustau, M., Sibony, O. and Alberti, C. (2011) Using and reporting the Delphi method for selecting healthcare quality indicators: a systematic review, *PLoS one*, 6(6): p.e20476; and Powell, C. (2003) The Delphi technique: myths and realities. *J Adv. Nurs.*, 41: 376–382

<sup>4</sup> Rowe, G. and Bolger, F. (2016) Final report on 'the identification of food safety priorities using the Delphi technique' [http://www.efsa.europa.eu/sites/default/files/scientific\\_output/files/main\\_documents/1007e.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1007e.pdf)

#### *Microbiological:*

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

#### *Environmental:*

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

#### *Nutrition:*

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

### **1.1.1 National Food Crime Unit**

In late March the Food Standards Agency (FSA) published<sup>5</sup> the first assessment of food crime in the UK, the Food Crime Annual Strategic Assessment (FCASA). Readers are referred to the FCASA for a list of strategic food crime priorities. There is some overlap with the above EFSA data, in relation to meat speciation issues.

### **1.1.2 Incidents**

In June 2016 the FSA published<sup>6</sup> its annual report of 2015 food incidents. It showed that in 2015, the FSA and Food Standards Scotland (FSS) were notified of, investigated and managed 1,514 food, feed and environmental contamination incidents in the UK. The overall number of incidents was similar to those seen in recent years. However, in most categories, the numbers of incidents differ considerably from year to year. The four largest contributors in 2015 were:

---

<sup>5</sup> <https://www.food.gov.uk/news-updates/news/2016/15017/the-food-standards-agency-fsa-has-today-published-the-first-assessment-of-food-crime-in-the-uk>

<sup>6</sup> <http://www.food.gov.uk/news-updates/news/2016/15190/fsa-annual-report-of-incidents-2015-published>

- Pathogenic micro-organisms (18%)
- Allergens (14%). The number of allergen incidents has increased from 89 in 2013 to 206 in 2015. This may be related to new rules on providing allergen ingredients information from December 2014
- Chemical contamination (other) (12%) (fires were the cause of almost all)
- Residues of veterinary medicinal products (8%).

In July 2016 the FSA published the continuing series of within year lists of incidents. Over the three month period, April to June 2016 FSA issued 47 food notices, of which 25 were allergy alerts, with the top three undeclared allergens being milk, gluten, and soya.<sup>7</sup>

The FSA review of an investigation in September 2014 where there were reports of the presence of soya, a potential allergenic risk, in wheat flour was covered in previous quarterly reports.<sup>8</sup>

## 1.2 Information management

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

A recent United Nations publication outlines a framework for integrated agrifood information management, taking into account the functional needs of various stakeholders along the supply chain. The benefits as well as challenges involved in developing a comprehensive system are discussed. Some examples of existing paperless systems – which are considered good practices for agrifood trade – are also included together with the list of relevant international standards to be taken into account when implementing the systems. Practical recommendations for, and milestones in the enhancement of agrifood information systems for trade facilitation are provided, including a recommendation to develop a Single Window for Agrifood Trade (SWAT). This publication is aimed mainly at government officials involved in overseeing and making policies related to agrifood trade. It is also relevant to the private sector (both existing and potential traders), associations and any agrifood supply-chain stakeholders interested in making agrifood trade both safer and more efficient. This policy guide builds on the series of technical and legal guides produced by UNNExT to facilitate paperless trade implementation.<sup>9</sup> Previous guides are also available.<sup>10</sup>

---

<sup>7</sup> <https://www.food.gov.uk/news-updates/news/2016/15370/fsa-publishes-list-of-incidents-for-april-to-june-2016>

<sup>8</sup> <https://www.food.gov.uk/sites/default/files/soya-in-wheat.pdf>

<sup>9</sup> Information management in agrifood chains: towards an integrated paperless framework for agrifood trade facilitation  
<http://unnex.unescap.org/pub/agriguide15.pdf>

<sup>10</sup> <http://unnex.unescap.org>

## 2 Food safety

### 2.1 Food hypersensitivity

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.<sup>11,12,13,14</sup> Significant recent developments in the area include the conviction of Mohammed Zaman at Teesside Crown Court for manslaughter following the death of a peanut allergic customer who had a reaction to a curry.<sup>15</sup>

Following the cumin and mahaleb cases new guidance launched on 7 June will provide 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.<sup>16,17</sup>

Changes to European legislation took effect in mid-2016 which affect gluten-free labelling. Regulation (EC) No 41/2009 provided a legal framework around the term gluten-free and was repealed on 20 July 2016. From this date, rules relating to gluten are provided by Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC), and Commission Implementing Regulation (EU) No 828/2014<sup>18</sup>; national provisions will allow enforcement at UK level.<sup>19</sup>

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<sup>-1</sup> 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<sup>-1</sup> 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<sup>-1</sup>.

National provisions were made by the Food Information (Scotland) Amendment Regulations 2016,<sup>191,20</sup> 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

---

<sup>11</sup> 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

<sup>12</sup> 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

<sup>13</sup> 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

<sup>14</sup> 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

<sup>15</sup> <http://www.bbc.co.uk/news/uk-england-36360111>

<sup>16</sup> <https://www.fdf.org.uk/news.aspx?article=7539>

<sup>17</sup> <https://www.fdf.org.uk/herbs-spices-guidance.aspx>

<sup>18</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1471529878473&uri=CELEX:32014R0828>

<sup>19</sup> <https://www.coeliac.org.uk/about-us/news/changes-to-european-legislation-on-gluten-free-labelling/>

<sup>20</sup> <http://www.legislation.gov.uk/ssi/2016/191/contents/made>

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.<sup>21</sup> 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 2016<sup>22</sup> which revoke the Foodstuffs Suitable for People Intolerant to Gluten (Wales) Regulations 2010.

## 2.2 Contaminants

Regulation (EC) No 1881/2006 remains the primary European legislation, the latest consolidated version of which was published in April 2016.<sup>23</sup> This is a measure that is frequently updated and almost always features in our quarterly updates. A useful summary of contaminant information is available on the European Commission website.<sup>24</sup>

### 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.<sup>25</sup>

### 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.

### 2.2.3 Dioxins and polychlorinated biphenyls (PCBs)

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

---

<sup>21</sup> <https://www.food.gov.uk/sites/default/files/food-information-regulations-ni-2016.pdf>

<sup>22</sup> <http://www.legislation.gov.uk/wsi/2016/664/made>

<sup>23</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1466704439817&uri=CELEX:02006R1881-20160401>

<sup>24</sup> [http://ec.europa.eu/food/safety/chemical\\_safety/contaminants/index\\_en.htm](http://ec.europa.eu/food/safety/chemical_safety/contaminants/index_en.htm)

<sup>25</sup> [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](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)

May 2016 Commission Recommendation (EU) 2016/688 established monitoring and management of the presence of dioxins and PCBs in fish and fishery products from the Baltic region. Certain fish and fishery products from the Baltic region exceed regularly the maximum levels set in Regulation 1881/2006 and the Recommendation sets out minimum sampling levels and other requirements for Denmark, Germany, Poland, Latvia, Estonia, Lithuania, Finland and Sweden.<sup>26</sup>

The International Agency for Research on Cancer, IARC, has concluded that there is sufficient evidence in humans for the carcinogenicity of PCBs and polybrominated biphenyls (PBBs) which were upgraded to Group 2A, probably carcinogenic to humans.<sup>27</sup>

#### **2.2.4 JECFA**

The eightieth report of the Joint FAO/WHO Expert Committee on Food Additives, JECFA, discussed the contaminants acrylamide, cadmium (impact assessment of different maximum limits), ethyl carbamate, inorganic tin, polybrominated diphenyl ethers and polycyclic aromatic hydrocarbons.<sup>28</sup>

### **2.3 Non regulated contaminants**

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

#### **2.3.1 Acrylamide**

The November 2015 the FSA update<sup>29</sup> on acrylamide remains highly relevant. The report looks at how the chemical was first identified, what the risks are to consumers, and how the FSA and industry are reacting to this risk.<sup>30</sup>

#### **2.3.2 Apricot kernels – cyanide**

EFSA have issued a scientific opinion on the acute health risks related to the presence of cyanogenic glycosides, mainly amygdalin, in raw apricot kernels and products therefrom. Amygdalin produces cyanide, by chewing or grinding, which is of high acute toxicity in humans. The estimated maximum quantity of apricot kernels (or raw apricot material) that can be consumed without exceeding the acute reference dose is 0.06 and 0.37 g in toddlers and adults, respectively. Thus the acute reference dose would be exceeded by consumption of one small kernel in toddlers, while adults could consume three small kernels. However, consumption of less than half of a large kernel could already exceed the acute reference dose in adults.<sup>31</sup>

---

<sup>26</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AAOJ.L\\_2016.118.01.0016.01.ENG](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AAOJ.L_2016.118.01.0016.01.ENG)

<sup>27</sup> <https://monographs.iarc.fr/ENG/Monographs/vol107/mono107-F01-F02.pdf>

Lauby-Secretan B, Loomis D, Grosse Y, El Ghissassi F, Bouvard V, Benbrahim-Tallaa L et al. ; International Agency for Research on Cancer Monograph Working Group IARC, Lyon, France (2013). Carcinogenicity of polychlorinated biphenyls and polybrominated biphenyls. *Lancet Oncol*, 14(4):287–8. doi:10.1016/S1470- 2045(13)70104-9 PMID:23499544

<sup>28</sup> Evaluation of certain food contaminants, [http://apps.who.int/iris/bitstream/10665/43258/1/WHO\\_TRS\\_930\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/43258/1/WHO_TRS_930_eng.pdf)

<sup>29</sup> <https://www.food.gov.uk/news-updates/news/2015/14655/chief-scientific-advisor-s-report-acrylamide>

<sup>30</sup> <https://www.food.gov.uk/sites/default/files/csa-acrylamide-report.PDF>

<sup>31</sup> [http://www.efsa.europa.eu/en/press/news/160427?mc\\_cid=127fb196ca&mc\\_eid=f1b5809dbc](http://www.efsa.europa.eu/en/press/news/160427?mc_cid=127fb196ca&mc_eid=f1b5809dbc)

### 2.3.3 Glycerol based process contaminants (MCPD and GE)

EFSA have assessed<sup>32</sup> the risks for public health of glycidyl fatty acid esters (GE), 3-monochloropropanediol (3-MCPD), and 2-monochloropropanediol (2-MCPD) and their fatty acid esters. These substances form during food processing, in particular, when refining vegetable oils at high temperatures (approx. 200°C).

The highest levels of GE, as well as 3-MCPD and 2-MCPD (including esters) were found in palm oils and palm fats, followed by other oils and fats. For consumers aged three and above, margarines and “pastries and cakes” were the main sources of exposure to all substances.

### 2.3.4 Endocrine disruptors

Endocrine disruptors are substances that interfere with the functioning of hormones, with potentially harmful effects on health. A wide range of chemicals are suspected of being responsible for endocrine-disrupting activity. Defining scientific criteria for their identification is highly complex and has important repercussions for a wide range of stakeholders. There is a lack of consensus among both scientists and regulators. Work on the issue has been conducted at UK, EU and international level. The European Commission's delay in adopting scientific criteria has provoked strong reactions from various stakeholders.

In a judgment delivered on 16 December 2015, the General Court of the Court of Justice of the EU found that the Commission had breached European Union law by failing to act on endocrine disruptors. It concluded that the Commission did not comply with its clear obligation to specify scientific criteria for the identification of chemicals that have endocrine-disrupting properties by 13 December 2013. In addition, it stated that there was no requirement to carry out an impact assessment, which the Commission had suggested was necessary to evaluate the various possible options prior to taking its decision.<sup>33</sup> The background to these issues and the Court judgement were examined in a briefing produced in April 2016 by the European Parliamentary Research Service.<sup>34</sup> The Commission published in June 2016 draft measures setting out scientific criteria for the determination of endocrine disruptors in the context of the EU legislation on plant protection products and biocidal products<sup>35, 36</sup>

### 2.3.5 Nickel

The Hellenic Food Authority asked EFSA to evaluate the risk to human health from the presence of nickel in food, particularly in vegetables. The EFSA Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) decided to extend the risk assessment to drinking water and adopted the Scientific Opinion on the risks to public health related to the presence of nickel in food and drinking water<sup>37</sup>. This opinion identified reproductive and developmental toxicity as the critical effect for the risk characterisation of chronic oral exposure to nickel. Eczematous flare-up reactions and worsening of allergic reactions were identified as the critical effect for acute oral exposure to nickel of nickel-sensitised humans. Commission Recommendation (EU) 2016/1111

---

<sup>32</sup> <http://www.efsa.europa.eu/en/press/news/160503a>

<sup>33</sup> [http://www.europarl.europa.eu/thinktank/en/document.html?reference=EPRS\\_BRI\(2016\)581986](http://www.europarl.europa.eu/thinktank/en/document.html?reference=EPRS_BRI(2016)581986)

<sup>34</sup> [http://www.europarl.europa.eu/RegData/etudes/BRIE/2016/581986/EPRS\\_BRI\(2016\)581986\\_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/BRIE/2016/581986/EPRS_BRI(2016)581986_EN.pdf)

<sup>35</sup> [http://ec.europa.eu/health/endocrine\\_disruptors/docs/com\\_2016\\_350\\_en.pdf](http://ec.europa.eu/health/endocrine_disruptors/docs/com_2016_350_en.pdf)

<sup>36</sup> [http://ec.europa.eu/health/endocrine\\_disruptors/policy/index\\_en.htm](http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm)

<sup>37</sup> EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain) (2015) Scientific Opinion on the risks to public health related to the presence of nickel in food and drinking water, EFSA Journal, 13(2):4002, 202 pp doi:10.2903/j.efsa.2015.4002

of 6 July 2016 therefore asked member states to monitor for nickel in certain foods.<sup>38</sup> (See also feed below, 6.1.3.)

## 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.<sup>39</sup>

Commission Regulation (EU) 2016/441 of 23 March 2016 amended Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council to permit the use of steviol glycosides (E 960) as a sweetener in mustard with a limit of 120 mg kg<sup>-1</sup> as steviol equivalents.<sup>40</sup> Commission Regulation (EU) 2016/479 of 1 April 2016 amended Annex II to permit the use of steviol glycosides in certain energy-reduced or “with no added sugars” beverages (coffee, tea, cappuccino (maximum 30 mg kg<sup>-1</sup>) and malt-based and chocolate/cappuccino flavoured (maximum 20 mg kg<sup>-1</sup>).<sup>41</sup>

Annex II was also amended by Commission Regulation (EU) 2016/683 of 2 May 2016 to extend the authorised use of propionic acid preservative to tortillas to a maximum of 2000 mg kg<sup>-1</sup>.<sup>42</sup>

The status of food additives in caseinates was clarified by aligning Annex II with the provisions of Directive (EU) 2015/2203<sup>43</sup> on caseins and caseinates intended for human consumption. A food category “edible caseinates” was established and the additives authorised in edible caseinates included with the respective conditions of use by Commission Regulation (EU) 2016/691 of 4 May 2016.<sup>44</sup> Compositional standards for caseinates are given in the Directive.

The seventy-ninth meeting of the Joint FAO/WHO Expert Committee on Food Additives, JECFA, discussed the safety evaluation of certain food additives with a view to recommending acceptable daily intakes (ADIs) and to preparing specifications for identity and purity. The first part of the report contains a general discussion of the principles governing the toxicological evaluation and assessment of intake of food additives. A summary follows of the Committee's evaluations of technical, toxicological and intake data for certain food additives: branching glycosyltransferase from *Rhodothermus obamensis* expressed in *Bacillus subtilis*, cassia gum, cyclamic acid and its salts (dietary exposure assessment), cyclotetraglucose and cyclotetraglucose syrup, ferrous ammonium phosphate, glycerol ester of gum rosin, glycerol ester of tall oil rosin, lycopene from all sources, lycopene extract from tomato, mineral oil (low and medium viscosity) class II and class III, octenyl succinic acid modified gum arabic, sodium hydrogen sulfate and sucrose oligoesters type I and type II. Specifications for the following food additives were revised: diacetyltartaric acid and fatty acid esters of glycerol, ethyl lauroyl arginate, glycerol ester of wood rosin, nisin preparation, nitrous oxide, pectins, starch sodium octenyl succinate, tannic acid, titanium dioxide and triethyl citrate. Annexed to the report are tables summarizing the Committee's recommendations for intakes and toxicological evaluations of the food additives considered.<sup>45</sup>

---

<sup>38</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1471533458929&uri=CELEX:32016H1111>

<sup>39</sup> [http://ec.europa.eu/food/food/FAEF/additives/guidance\\_en.print.htm](http://ec.europa.eu/food/food/FAEF/additives/guidance_en.print.htm)

<sup>40</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1466595930807&uri=CELEX:32016R0441>

<sup>41</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2016.087.01.0001.01.ENG&toc=OJ:L:2016:087:TOC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.087.01.0001.01.ENG&toc=OJ:L:2016:087:TOC)

<sup>42</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2016.117.01.0028.01.ENG&toc=OJ:L:2016:117:TOC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.117.01.0028.01.ENG&toc=OJ:L:2016:117:TOC)

<sup>43</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1466676596182&uri=CELEX:32015L2203>

<sup>44</sup> [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](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)

<sup>45</sup> <http://www.ncbi.nlm.nih.gov/pubmed/20942228>

### 2.4.1 Sulphites

In April 2014 EFSA published a major review of the widely used additives sulphur dioxide and the sulphites group, which are included as a legislated allergen group in the Food Information Regulation 1169/2011 owing to possible intolerance reactions and recorded probable fatalities in consumers sensitive to sulphites in food. EFSA also noted that endogenous sulphites can be generated as a consequence of the body's normal processing of sulphur-containing amino acids and that sulphites may occur as a consequence of fermentation and are naturally present in a number of foods and beverages. EFSA confirmed that although the toxicological database was limited, the current group ADI of 0.7 mg SO<sub>2</sub> 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.<sup>46</sup>

### 2.4.2 Additives in wine

Commission Regulation (EC) No 606/2009 lays down authorised oenological practices (Annex I A). The International Organisation of Vine and Wine (OIV) adopted new oenological practices concerning the use of malolactic fermentation activators, and the treatment of wine and must with glutathione. In accordance with Article 80(3)(b) of Regulation (EC) No 1308/2013, when authorising oenological practices for wine, the Commission must take into account the protection of human health. Glutathione is used for its antioxidant properties and remains active in the final product, therefore it is a food additive. However it is not currently included in Annex II to Regulation (EC) No 1333/2008 hence its use in wine and must cannot be authorised unless and until it is included in the Union list of food additives, on the basis of an EFSA positive opinion. However Commission Delegated Regulation (EU) 2016/765 of 11 March 2016 did amend Regulation 606/2009 to allow use of certain malolactic fermentation activators as described in 2016/765.<sup>47</sup>

### 2.4.3 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<sup>48</sup>. Commission Regulation (EU) 2016/637 of 22 April 2016<sup>49</sup> removed the following flavour compounds from the EU permitted list: 2,6,6-trimethyl-1-cyclohexen-1-carboxaldehyde (FL No 05.121), myrtenyl formate (FL No 09.272), myrtenyl-2-methylbutyrate (FL No 09.899), and myrtenyl-3-methylbutyrate (FL No 09.900). This was as a result of an EFSA opinion, on the basis of submitted data, that the representative compound for this class of flavouring, p-mentha-1,8-dien-7-al (FL No 05.117), is genotoxic in vivo, has already been removed from the list and hence its related compounds also pose a potential safety concern. Following this, Commission Regulation (EU) 2016/1244 of 28 July 2016<sup>50</sup> amended Annex I to Regulation 1334/2008 to limit the use of the compounds related to p-mentha-1,8-dien-7-al (FL No 05.117), namely p-mentha-1,8-dien-7-ol (FL No 02.060), myrtenol (FL No 02.091), myrtenal (FL No 05.106), p-mentha-1,8-dien-7-yl acetate (FL No 09.278) and myrtenyl acetate (FL No 09.302) to certain categories of food pending a full evaluation by EFSA.

---

<sup>46</sup> [http://www.efsa.europa.eu/sites/default/files/scientific\\_output/files/main\\_documents/4438.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4438.pdf)

<sup>47</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1471533458929&uri=CELEX:32016R0765>

<sup>48</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1445980490072&uri=CELEX:02008R1334-20150729>

<sup>49</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2016.108.01.0024.01.ENG&toc=OJ:L:2016:108:TOC&mc\\_cid=127fb196ca&mc\\_eid=f1b5809dbc](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.108.01.0024.01.ENG&toc=OJ:L:2016:108:TOC&mc_cid=127fb196ca&mc_eid=f1b5809dbc)

<sup>50</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1244>

## 2.5 Food contact materials

Regulation (EC) No 1935/2004<sup>51</sup> 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.<sup>52</sup>

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.<sup>53, 54</sup>

In August 2016 Regulation 10/2009 was extensively amended by Commission Regulation (EU) 2016/1416.<sup>55</sup> Recent EFSA opinions have been incorporated and textual errors corrected, the definition 'hot-fill' has been clarified, and other technical clarifications made.

Commission Regulation 2015/1906<sup>56</sup> has amended Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods. The amendment clarifies regulatory procedures consequent upon Decision 1999/468/EC having been replaced by Regulation (EU) No 182/2011.

## 2.6 Marine biotoxins

No new centrally published updates in this quarter.

## 2.7 Pesticides

Commission Implementing Regulation 2015/595<sup>57</sup> sets out a coordinated multiannual control programme of the EU for 2016, 2017 and 2018 to ensure compliance with maximum residue levels (MRLs) of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

Regulation (EC) No 396/2005 governs MRLs of pesticides in or on food and feed of plant and animal origin; Annexes II, III and V to the regulation are regularly amended as regards MRLs and can be seen on the EU Pesticides Database.<sup>58, 59</sup>

---

<sup>51</sup> See EUR-Lex for up to date versions of legislation: <http://eur-lex.europa.eu/homepage.html>

<sup>52</sup> 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>

<sup>53</sup> [http://ec.europa.eu/food/safety/chemical\\_safety/food\\_contact\\_materials/legislation/index\\_en.htm](http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation/index_en.htm)

<sup>54</sup> [http://ec.europa.eu/food/safety/chemical\\_safety/food\\_contact\\_materials/index\\_en.htm](http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/index_en.htm)

<sup>55</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1416>

<sup>56</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2015.278.01.0011.01.ENG](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.278.01.0011.01.ENG)

<sup>57</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2015.099.01.0007.01.ENG](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.099.01.0007.01.ENG)

<sup>58</sup> <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>

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.<sup>60</sup> Regulation 1107/2009 is implemented by Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011<sup>61</sup> which is frequently updated.

In May 2016 rolling results from the government's monitoring programme in 2016 to check home-produced and imported food for any pesticide residues were published for January to March 2016.<sup>62</sup>

### 2.7.1 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.<sup>63</sup>

## 2.8 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. In April 2016 Commission Implementing Regulation (EU) 2016/759 prescribed lists of third countries, parts of third countries and territories from which Member States are to authorise the introduction into the Union of certain products of animal origin intended for human consumption, laying down certificate requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC. The products covered are:<sup>64</sup>

- (a) Frogs' legs
- (b) snails
- (c) gelatine and collagen
- (d) raw materials for the production of gelatine and collagen
- (e) treated raw materials for the production of gelatine and collagen
- (f) honey, royal jelly and other products of apiculture
- (g) the following highly refined products:
  - (i) chondroitin sulphate
  - (ii) hyaluronic acid
  - (iii) other hydrolysed cartilage products
  - (iv) chitosan
  - (v) glucosamine
  - (vi) rennet
  - (vii) isinglass
  - (viii) amino acids that are authorised as food additives.

---

<sup>59</sup> [http://ec.europa.eu/food/plant/pesticides/max\\_residue\\_levels/index\\_en.htm](http://ec.europa.eu/food/plant/pesticides/max_residue_levels/index_en.htm)

<sup>60</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474202948544&uri=CELEX:02009R1107-20140630> (but see EUR-Lex for latest version)

<sup>61</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474199567547&uri=CELEX:32011R0540> (but see EUR-Lex for latest version)

<sup>62</sup> <https://www.gov.uk/government/publications/pesticide-residues-in-food-rolling-monitoring-results-for-2016>

<sup>63</sup> <https://echa.europa.eu/regulations/biocidal-products-regulation>

<sup>64</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1469454004085&uri=CELEX:32016R0759>

## 2.9 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.

Council Regulation (Euratom) 2016/52<sup>65</sup> 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 new Welsh private water supply regulations covering monitoring of radioactivity in water at 2.13 below.

## 2.10 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.<sup>66</sup>

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.<sup>67</sup>

## 2.11 Veterinary residues

Commission Regulation (EU) No 37/2010 of 22 December 2009 deals with MRLs of veterinary medicinal products in foodstuffs of animal origin. Domestic effect is given by the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015<sup>68</sup> and, in Northern Ireland, by the Animal and Animal Products (Examination for Residues and Maximum Residue Limits) (Northern Ireland) 2016 (SR 54)<sup>69</sup>.

Regulation (EU) No 37/2010 is regularly amended as regards MRLs. Further information is available from the European Medicines Agency (EMA)<sup>70</sup> and on the European Commission website.<sup>71</sup> 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. For example at 17<sup>th</sup> September 2016 the latest

---

<sup>65</sup> [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](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)

<sup>66</sup> [http://ec.europa.eu/food/safety/biosafety/food\\_borne\\_diseases/tse\\_bse/index\\_en.htm](http://ec.europa.eu/food/safety/biosafety/food_borne_diseases/tse_bse/index_en.htm)

<sup>67</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1396>

<sup>68</sup> [http://www.legislation.gov.uk/ukxi/2015/787/pdfs/ukxi\\_20150787\\_en.pdf](http://www.legislation.gov.uk/ukxi/2015/787/pdfs/ukxi_20150787_en.pdf)

<sup>69</sup> [http://www.legislation.gov.uk/nisr/2016/54/pdfs/nisr\\_20160054\\_en.pdf](http://www.legislation.gov.uk/nisr/2016/54/pdfs/nisr_20160054_en.pdf)

<sup>70</sup> [http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000165.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000165.jsp)

<sup>71</sup> [http://ec.europa.eu/health/documents/community-register/index\\_en.htm](http://ec.europa.eu/health/documents/community-register/index_en.htm)

amendment to the regulation was that of 3<sup>rd</sup> June 2016 and an amendment of 31<sup>st</sup> August Commission Implementing Regulation (EU) 2016/1444<sup>72</sup> on MRLs for hydrocortisone aceponate had not been included. It is therefore best to search EUR-Lex from the date of the last amendment to ensure full coverage.

Toxicological evaluation of veterinary residues is carried out by the Joint FAO/WHO Expert Committee on Food Additives, JECFA, an international expert scientific committee administered jointly by the Food and Agriculture Organization of the United Nations, FAO, and the World Health Organization, WHO.<sup>73</sup> For example JECFA most recent publications in this area include general background information and toxicological evaluations of Diflubenzuron, Ivermectin, Sisapronil, and Teflubenzuron.<sup>74, 75</sup>

The lists of National Reference Laboratories for veterinary residues was amended in August 2016 by Commission Implementing Decision (EU) 2016/1365 amending Decision 98/536/EC.<sup>76</sup>

## 2.12 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'.<sup>77</sup> HACCP (Hazard Analysis and Critical Control Point) is a key system that helps food business operators address food hygiene.<sup>78</sup> Food Hygiene is controlled legislatively by Food Safety and Hygiene Regulations, currently the Food Safety and Hygiene (England) Regulations 2013<sup>79</sup> with equivalents in Wales<sup>80</sup>, Scotland<sup>81</sup> and Northern Ireland<sup>82</sup>. 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.<sup>83</sup> Guidance on microbiological criteria is available from Public Health England<sup>84</sup> and from IFST on aspects such as Shigatoxin-producing *E. coli*, fresh produce safety, foodborne viral infections, campylobacter, cyclospora, and cryptosporidium<sup>85</sup>.

Food Hygiene (Amendment) Regulations were made in England., Wales, Scotland and Northern Ireland in the quarter coming into force in October and make various amendments provide for the execution and enforcement of Commission Implementing Regulation (EU) 2015/1375 laying down specific rules on official controls for *Trichinella* in meat.<sup>86, 87, 88, 89</sup>

---

<sup>72</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1444>

<sup>73</sup> <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/>

<sup>74</sup> [http://apps.who.int/iris/bitstream/10665/205797/1/9789241660723\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/205797/1/9789241660723_eng.pdf)

<sup>75</sup> [http://apps.who.int/iris/bitstream/10665/204670/1/9789240695504\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/204670/1/9789240695504_eng.pdf)

<sup>76</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1365>

<sup>77</sup> <https://www.food.gov.uk/business-industry/food-hygiene>

<sup>78</sup> <https://www.food.gov.uk/business-industry/food-hygiene/haccp>

<sup>79</sup> <http://www.legislation.gov.uk/uksi/2013/2996/note/made>

<sup>80</sup> Food Hygiene (Wales) Regulations 2006 with many subsequent amendments

<sup>81</sup> Food Hygiene (Scotland) Regulations 2006 with many subsequent amendments

<sup>82</sup> The Food Hygiene Regulations (Northern Ireland) 2006 with many subsequent amendments

<sup>83</sup> <https://www.food.gov.uk/business-industry/guidancenotes/hygguid/microbiolreg>

<sup>84</sup> PHE, 2009, Ready-to-eat foods: microbiological safety assessment guidelines

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

<sup>85</sup> <http://www.ifst.org/knowledge-centre/information-statements>

<sup>86</sup> The Food Safety and Hygiene (England) (Amendment) Regulations 2016

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

<sup>87</sup> The Food Hygiene (Wales) (Amendment) Regulations 2016, <http://www.legislation.gov.uk/cy/wsi/2016/845/made>

<sup>88</sup> 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/ssi/2016/260/pdfs/ssi_20160260_en.pdf)

<sup>89</sup> <http://www.legislation.gov.uk/nistr/2016/345/contents/made>

### 2.12.1 Food hygiene rating schemes

Food Hygiene Rating Schemes help consumers choose where to eat out or shop for food by giving them information about the hygiene standards in restaurants, takeaways and food shops<sup>90</sup>. 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. In the quarter the schemes in Wales and Northern Ireland gained statutory force with the Food Hygiene Rating (Promotion of Food Hygiene Rating) (Wales) Regulations 2016, No. 429 (W. 138)<sup>91</sup> which come into force on 28 November 2016 and The Food Hygiene Rating Act (Northern Ireland) 2016<sup>92</sup>. In Wales the regulation applies to establishments which supply takeaway food and requires a conspicuous notice in Welsh and English to indicate the availability of the business food hygiene rating. The Food Hygiene Rating Regulations (Northern Ireland) 2016 no. 313<sup>93</sup> and the Food Hygiene Rating (Transitional Provisions) Order (Northern Ireland) 2016 no. 314<sup>94</sup> 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 appoints 7<sup>th</sup> October 2016 for the coming onto operation of the Act<sup>95</sup>. The hygiene rating is displayed on the rating sticker given by the local authority following inspection; in England Wales and Northern Ireland the rating ranges from '5' which means the food hygiene standards are very good, down to '0' where urgent improvement is necessary. In England FSA is exploring how a viable statutory scheme could be delivered in the future in line with the FSA's 'Regulating our Future' programme and in the meantime the current voluntary scheme in England is being aligned with the statutory schemes in Wales and Northern Ireland as far as possible without legislative requirements.

### 2.13 Water for human consumption

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

The primary EU law on supplied water is Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, alongside Directive 2009/54/EC on the exploitation and marketing of natural mineral waters<sup>96</sup> (recast)<sup>97</sup> and Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters.<sup>98</sup>

---

<sup>90</sup> <https://www.food.gov.uk/business-industry/hygieneratings>

<sup>91</sup> [http://www.legislation.gov.uk/wsi/2016/429/pdfs/wsi\\_20160429\\_mi.pdf](http://www.legislation.gov.uk/wsi/2016/429/pdfs/wsi_20160429_mi.pdf)

<sup>92</sup> Food Hygiene Rating Act (Northern Ireland) 2016, Ch 3 <http://origin-www.legislation.gov.uk/nia/2016/3/enacted>

<sup>93</sup> <http://www.legislation.gov.uk/nisr/2016/313/made>

<sup>94</sup> <http://www.legislation.gov.uk/nisr/2016/314/made>

<sup>95</sup> <http://www.legislation.gov.uk/nisr/2016/328/made/data.pdf>

<sup>96</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1453734625466&uri=CELEX:32009L0054>

<sup>97</sup> Which repeals and replaces Directive 80/777/EEC.

<sup>98</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1453734764128&uri=CELEX:32003L0040>

Domestic implementation of the latter two is by:

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

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015<sup>99, 100</sup> amended, in this quarter, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007 (“the 2007 Regulations”) by implementing, in relation to spring water and drinking water in a bottle, Council Directive 2013/51/Euratom laying down the requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (OJ L 296, 7.11.13, p.12). Regulation 3 makes consequential amendments to the interpretation provisions in regulation 2 of the 2007 Regulations. Regulation 4 amends regulation 16 of the 2007 Regulations to specify the monitoring and sampling requirements required by Food Authorities. Similar legislation has been enacted in Wales by the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015<sup>101</sup> (SI 1867, W274) and in Northern Ireland with the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2015<sup>102</sup> (SR 365).

Commission Directive 2015/1787<sup>103</sup> 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)<sup>104</sup> 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

---

<sup>99</sup> [http://www.legislation.gov.uk/ssi/2015/363/pdfs/ssi\\_20150363\\_en.pdf](http://www.legislation.gov.uk/ssi/2015/363/pdfs/ssi_20150363_en.pdf)

<sup>100</sup> [http://www.legislation.gov.uk/ssi/2015/363/pdfs/ssics\\_20150363\\_en.pdf](http://www.legislation.gov.uk/ssi/2015/363/pdfs/ssics_20150363_en.pdf) correction slip

<sup>101</sup> [http://www.legislation.gov.uk/wsi/2015/1867/pdfs/wsi\\_20151867\\_mi.pdf](http://www.legislation.gov.uk/wsi/2015/1867/pdfs/wsi_20151867_mi.pdf)

<sup>102</sup> [http://www.legislation.gov.uk/nisr/2015/365/pdfs/nisr\\_20150365\\_en.pdf](http://www.legislation.gov.uk/nisr/2015/365/pdfs/nisr_20150365_en.pdf)

<sup>103</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2015.260.01.0006.01.ENG](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.260.01.0006.01.ENG)

<sup>104</sup> <http://www.assembly.wales/laid%20documents/sub-ld10651/sub-ld10651-e.pdf>

2010 Regulations. The new Part 3 makes provision for additional sampling and analysis requirements in relation to the radioactive substances parameters listed in the new Table D in Part 3 of Schedule 1.

The Water Supply (Water Quality) Regulations 2016, 614<sup>105</sup>, 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, coming into force 27 June 2016.<sup>106</sup> They revoke and replace the Private Water Supplies Regulations 2009 (SI 2009/3101).

## 2.14 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.<sup>107</sup>

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;

---

<sup>105</sup> [http://www.legislation.gov.uk/uksi/2016/614/pdfs/ukxi\\_20160614\\_en.pdf](http://www.legislation.gov.uk/uksi/2016/614/pdfs/ukxi_20160614_en.pdf)

<sup>106</sup> <http://www.legislation.gov.uk/uksi/2016/618/contents/made>

<sup>107</sup> <http://www.legislation.gov.uk/ukpga/2016/2/contents/enacted>

- Includes provision for civil sanctions – prohibition notices, premises notices, prohibition orders and premises orders (breach of the two orders will be a criminal offence) – to enable the police and local authorities to adopt a graded response to the supply of psychoactive substances in appropriate cases;
- Provides powers to stop and search persons, vehicles and vessels, enter and search premises in accordance with a warrant, and to seize and destroy psychoactive substances.

Further information including explanatory notes is available<sup>108</sup> as well as Home Office guidance for local authorities on taking action against “head shops” selling psychoactive substances.<sup>109</sup>

Certain enabling powers were also made with UK applicability: the Psychoactive Substances Act 2016 (Consequential Amendments) Regulations 2016<sup>110</sup>, the Psychoactive Substances Act 2016 (Commencement) Regulations 2016<sup>111</sup> and the Magistrates' Courts (Psychoactive Substances Act 2016) (Transfer of Proceedings) Rules 2016<sup>112</sup>.

The Psychoactive Substances Act 2016 (correction slip) noted Schedule 5, paragraph 8(2): “1A” should read “1ZA”<sup>113</sup>

Ensuring adequate access to internationally controlled drugs for medical and scientific purposes was set out in the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol. Later, psychotropic substances were also recognized as being indispensable for medical and scientific purposes. A supplement to the annual report of the International Narcotics Control Board (INCB) for 2015 analyses global access to narcotic drugs and psychotropic substances. It also reviews patterns and trends relating to consumption, as well as information provided by Member States on the policies and practices at the country level for ensuring the availability of these controlled substances, and the impediments thereto. The 1961 and 1971 Conventions indicate the primary interest of the international community in protecting the health and welfare of humankind by making these indispensable substances available for medical and scientific purposes while ensuring that there is no diversion or abuse.<sup>114</sup>

The Report of the International Narcotics Control Board for 2015 was published<sup>115</sup> and precursors and chemicals frequently used in the illicit manufacture of narcotic drugs and psychotropic substances were reported on in a publication of the International Narcotics Control Board for 2015 on the implementation of article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988.<sup>116</sup>

Council Implementing Decision (EU) 2016/1070 of 27 June 2016 placed 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one ( $\alpha$ -pyrrolidinovalerophenone,  $\alpha$ -PVP) under control measures as a potent psychostimulant, structurally related to cathinone and other substances controlled under the 1971

<sup>108</sup> <https://www.gov.uk/government/collections/psychoactive-substances-bill-2015>

<sup>109</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/410961/Guidance\\_for\\_local\\_authorities\\_on\\_taking\\_action\\_against\\_10.03.15.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/410961/Guidance_for_local_authorities_on_taking_action_against_10.03.15.pdf)

<sup>110</sup> <http://www.legislation.gov.uk/ukxi/2016/554/regulation/2/made>

<sup>111</sup> <http://www.legislation.gov.uk/ukxi/2016/553/contents/made>

<sup>112</sup> <http://www.legislation.gov.uk/ukxi/2016/546/made>

<sup>113</sup> [http://www.legislation.gov.uk/ukpga/2016/2/pdfs/ukpgacs\\_20160002\\_en.pdf](http://www.legislation.gov.uk/ukpga/2016/2/pdfs/ukpgacs_20160002_en.pdf)

<sup>114</sup> Availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes. - xii, 99pp.,

[http://www.incb.org/documents/Publications/AnnualReports/AR2015/English/Supplement-AR15\\_availability\\_English.pdf](http://www.incb.org/documents/Publications/AnnualReports/AR2015/English/Supplement-AR15_availability_English.pdf)

<sup>115</sup> <https://www.incb.org/incb/en/publications/annual-reports/annual-report-2015.html>

<sup>116</sup> [https://www.incb.org/documents/PRECURSORS/TECHNICAL\\_REPORTS/2014/2014-PreAR\\_E.pdf](https://www.incb.org/documents/PRECURSORS/TECHNICAL_REPORTS/2014/2014-PreAR_E.pdf)

United Nations Convention on Psychotropic Substances. Eight Member States have reported a total of 115 deaths and 191 acute intoxications where  $\alpha$ -PVP was detected.<sup>117</sup>

## 2.15 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<sup>118</sup>. 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.<sup>119</sup> 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<sup>120</sup>. 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.<sup>121</sup> This list is periodically updated; see for example (non-exhaustively) Commission Implementing Decision (EU) 2016/1659 of 13 September 2016<sup>122</sup> that introduced species of *Melaleuca* (Tea Tree oil) into the list.

In the UK Herbal medicines can be registered under the traditional herbal registration scheme and the Medicines and Healthcare products Regulatory Agency, MHRA, list of registered traditional herbal medicines is updated regularly.<sup>123</sup> A list of banned or restricted herbal products, including for example aconite, belladonna, kava-kava and ragwort, is available.<sup>124</sup>

Periodic assessment of herbal products takes place, for example recently the International Agency for Research on Cancer, IARC, of the World Health Organization published an evaluation of carcinogenic risks to humans of some drugs and herbal medicines. Whole leaf extract of aloe vera, ginkgo biloba extract, goldenseal root powder, kava extract and the pulegone component of pennyroyal oils were classified in IARC Group 2B (possibly carcinogenic to humans).<sup>125, 126</sup>

---

<sup>117</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1070>

<sup>118</sup> Walker, D.R., 2015, Report on the Regulation of Herbal Medicines and Practitioners, 26 march 2015, [http://www.dcscience.net/Report\\_on\\_Regulation\\_of\\_Herbal\\_Medicines\\_and\\_Practitioners.pdf](http://www.dcscience.net/Report_on_Regulation_of_Herbal_Medicines_and_Practitioners.pdf) (Accessed 17.09.2016)

<sup>119</sup> Directive 2001/83/EC <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474128484290&uri=CELEX:02001L0083-20121116>

<sup>120</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474128379997&uri=CELEX:32004L0024>

<sup>121</sup> [http://ec.europa.eu/health/human-use/herbal-medicines/index\\_en.htm](http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm)

<sup>122</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1659>

<sup>123</sup> <https://www.gov.uk/government/publications/herbal-medicines-granted-a-traditional-herbal-registration-thr>

<sup>124</sup> <https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients>

<sup>125</sup> <http://monographs.iarc.fr/ENG/Monographs/vol108/mono108.pdf>

<sup>126</sup> Grosse *et al.*, The Lancet Oncology, 14, 807 – 808, <http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045%2813%2970329-2/fulltext>

## 3 Consumer choice

### 3.1 Food labelling

The primary legislation is now Regulation 1169/2011<sup>127</sup> 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.<sup>128</sup> Domestic implementation is effected in England by the Food Information Regulations (SI 2014 No 1855)<sup>129</sup>, in Northern Ireland by the Food Information Regulations (Northern Ireland) 2014 (SR 2014 No 223)<sup>130</sup> and, in Wales the Food Information Regulations (Wales) 2014 (SI 2014 No 2303, W227)<sup>131</sup>. In Scotland implementation is by the Food Information Regulations (Scotland) 2014 (SSI 312)<sup>132</sup> which were amended in December 2015 by the Food Information (Miscellaneous Amendments) (Scotland) Regulations 2015 (SSI 410).<sup>133</sup> These make a set of small drafting amendments, for example clarifying aspects of the labelling of “alcohol-free”, “dealcoholized” and “low alcohol” drinks.

Information is available on the Commission website.<sup>134</sup> Guidance on nutrition labelling is also available on the Commission website.<sup>135</sup>

#### 3.1.1 Country of origin labelling

The Country of Origin of Certain Meats (England) Regulations 2015 (SI 518)<sup>136</sup> 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.<sup>137</sup>

Similar legislation has been enacted in Northern Ireland through The Country of Origin of Certain Meats Regulations (Northern Ireland) 2015<sup>138</sup> (SR 321) and in Wales by the Country of Origin of Certain Meats (Wales) Regulations 2015<sup>139</sup> (SI 1591, W177).

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

---

<sup>127</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF>

<sup>128</sup> <http://www.reading.ac.uk/foodlaw/label/links.htm>

<sup>129</sup> [http://www.legislation.gov.uk/ukSI/2014/1855/pdfs/ukSI\\_20141855\\_en.pdf](http://www.legislation.gov.uk/ukSI/2014/1855/pdfs/ukSI_20141855_en.pdf)

<sup>130</sup> [http://www.legislation.gov.uk/nisr/2014/223/pdfs/nisr\\_20140223\\_en.pdf](http://www.legislation.gov.uk/nisr/2014/223/pdfs/nisr_20140223_en.pdf)

<sup>131</sup> [http://www.legislation.gov.uk/wsi/2014/2303/pdfs/wsi\\_20142303\\_mi.pdf](http://www.legislation.gov.uk/wsi/2014/2303/pdfs/wsi_20142303_mi.pdf)

<sup>132</sup> [http://www.legislation.gov.uk/ssi/2014/312/pdfs/ssi\\_20140312\\_en.pdf](http://www.legislation.gov.uk/ssi/2014/312/pdfs/ssi_20140312_en.pdf)

<sup>133</sup> [http://www.legislation.gov.uk/ssi/2015/410/pdfs/ssi\\_20150410\\_en.pdf](http://www.legislation.gov.uk/ssi/2015/410/pdfs/ssi_20150410_en.pdf)

<sup>134</sup> [http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/proposed\\_legislation\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/proposed_legislation_en.htm)

<sup>135</sup> [http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm)

<sup>136</sup> [http://www.legislation.gov.uk/ukSI/2015/518/pdfs/ukSI\\_20150518\\_en.pdf](http://www.legislation.gov.uk/ukSI/2015/518/pdfs/ukSI_20150518_en.pdf)

<sup>137</sup> <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2015>

<sup>138</sup> [http://www.legislation.gov.uk/nisr/2015/321/pdfs/nisr\\_20150321\\_en.pdf](http://www.legislation.gov.uk/nisr/2015/321/pdfs/nisr_20150321_en.pdf)

<sup>139</sup> [http://www.legislation.gov.uk/wsi/2015/1519/pdfs/wsi\\_20151519\\_mi.pdf](http://www.legislation.gov.uk/wsi/2015/1519/pdfs/wsi_20151519_mi.pdf)

Ultimately it is the food manufacturers' responsibility not to mislead consumers with the labelling information that they provide.<sup>140</sup>

### 3.1.2 Meat products

The Products Containing Meat etc. Regulations 2014 enacted in England (e.g. SI 3001/2014<sup>141</sup>), 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<sup>142</sup>).

Similar Regulations have been enacted in Scotland with the Products Containing Meat etc. Regulations (Scotland) Regulations 2014 (SSI 289/2014)<sup>143</sup> which revokes the Meat Products (Scotland) Regulations 2004 (SSI 6/2004), the Meat Products (Scotland) Amendment Regulations 2008 (SSI 97/2008) and regulation 18(4) of the Food Additives (Scotland) Regulations 2009 (SSI 436/2009), and in Northern Ireland with the Products Containing Meat etc. Regulations (Northern Ireland) 2014<sup>144</sup> (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).<sup>145</sup>

### 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).<sup>146</sup>

### 3.1.4 Defra food labelling guidance

Defra have published guidance on the information that must be provided with food products to comply with the European Food Information to Consumers Regulation No 1169/2011 (FIC) and the Food Information Regulations 2014 (FIR).<sup>147</sup>

### 3.1.5 Organic food

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

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 in August 2016 was amended again by Commission Implementing

---

<sup>140</sup> <https://www.food.gov.uk/northern-ireland/news-updates/news/2016/15025/voluntary-labelling-of-country-of-origin>

<sup>141</sup> [http://www.legislation.gov.uk/ukxi/2014/3001/pdfs/ukxi\\_20143001\\_en.pdf](http://www.legislation.gov.uk/ukxi/2014/3001/pdfs/ukxi_20143001_en.pdf)

<sup>142</sup> <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review>

<sup>143</sup> [http://www.legislation.gov.uk/ssi/2014/289/pdfs/ssi\\_20140289\\_en.pdf](http://www.legislation.gov.uk/ssi/2014/289/pdfs/ssi_20140289_en.pdf)

<sup>144</sup> [http://www.legislation.gov.uk/nisr/2014/285/pdfs/nisr\\_20140285\\_en.pdf](http://www.legislation.gov.uk/nisr/2014/285/pdfs/nisr_20140285_en.pdf)

<sup>145</sup> [http://www.legislation.gov.uk/ssi/2016/24/pdfs/ssi\\_20160024\\_en.pdf](http://www.legislation.gov.uk/ssi/2016/24/pdfs/ssi_20160024_en.pdf)

<sup>146</sup> [http://ec.europa.eu/fisheries/documentation/publications/eu-new-fish-and-aquaculture-consumer-labels-pocket-guide\\_en.pdf](http://ec.europa.eu/fisheries/documentation/publications/eu-new-fish-and-aquaculture-consumer-labels-pocket-guide_en.pdf)

<sup>147</sup> <https://www.gov.uk/guidance/food-labelling-giving-food-information-to-consumers>

Regulation (EU) 2016/1330 as regards the arrangements for imports of organic products from third countries.<sup>148</sup>

Commission Implementing Regulation (EU) 2016/673 of 29 April 2016<sup>149</sup> amended Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 as regards micro-algae, juveniles and seed from non-organic bivalve shellfish hatcheries, certain oenological practices, reconstitution of a herd or a flock after high mortality of animals by health or catastrophic circumstances, and other administrative details. Micro-algae, like multi-cellular marine algae and phytoplankton, are already subject to detailed production rules under Article 6a of Regulation (EC) No 889/2008 when they are further used as feed for aquaculture animals and the rules were extended when they are used for food production. By the end of December 2015 all juveniles and seed from bivalve shellfish hatcheries should have been of organic production. However insufficient organic products were available and the deadline has been extended one year.

All foods sold as organic must originate from growers, processors and importers who are registered with an approved certification body and subject to regular inspection. In October 2015 Defra updated the list of UK approved organic control bodies.<sup>150</sup>

### 3.1.6 Net Quantities

Minor corrections were made to the Weights and Measures (Food) (Amendment) Regulations (Northern Ireland) 2016 No. 187 that originally came into operation on 18th 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.<sup>151</sup>

## 3.2 Food fraud/food crime

The European Commission IT tool to facilitate the exchange of administrative information between national authorities working to combat cross-border violations in Europe – known as the Administrative Assistance and Cooperation (AAC) system – was described in a previous report. In the wake of the horsemeat episode of 2013, the Commission<sup>152</sup> 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<sup>153</sup>. The AAC system will ensure that the Food Fraud Network works even more efficiently and is able to respond more swiftly to information requests.

On 30 March 2016 Europol announced the outcomes of Operation Opson V.<sup>154</sup> More than 10,000 tonnes and one million litres of hazardous fake food and drink had been seized in operations across 57 countries in an INTERPOL-Europol coordinated exercise to protect public health and safety. Seizures ranged from nearly nine tonnes of counterfeit sugar contaminated with fertilizer

---

<sup>148</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1330>

<sup>149</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2016.116.01.0008.01.ENG&toc=OJ:L:2016:116:TOC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.116.01.0008.01.ENG&toc=OJ:L:2016:116:TOC)

<sup>150</sup> <https://www.gov.uk/government/publications/organic-certification-list-of-uk-approved-organic-control-bodies>

<sup>151</sup> 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>

<sup>152</sup> [http://ec.europa.eu/food/safety/official\\_controls/food\\_fraud/horse\\_meat/index\\_en.htm](http://ec.europa.eu/food/safety/official_controls/food_fraud/horse_meat/index_en.htm)

<sup>153</sup> [http://ec.europa.eu/food/safety/official\\_controls/food\\_fraud/index\\_en.htm](http://ec.europa.eu/food/safety/official_controls/food_fraud/index_en.htm)

<sup>154</sup> <https://www.europol.europa.eu/content/largest-ever-seizures-fake-food-and-drink-interpol-europol-operation>

in Khartoum, Sudan to Italian officers recovering more than 85 tonnes of olives which had been “painted” with copper sulphate solutions to enhance their colour. Involving police, customs, national food regulatory bodies and partners from the private sector, checks were carried out at shops, markets, airports, seaports and industrial estates between November 2015 and February 2016. A number of arrests were made worldwide.

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.<sup>155</sup>

### 3.3 Genetically modified organisms

Regulation (EC) No 1829/2003 of the European Parliament and of the Council provides for the authorisation, labelling and supervision of genetically modified food and feed.<sup>156</sup> Pursuant to Regulation 1829/2003 three Commission Implementing Decisions were made on 22 July 2016 authorising the placing on the market of products containing, consisting of, or produced from genetically modified:

- Soybean FG72 (MST-FGØ72-2), Decision 2016/1215<sup>157</sup>
- Soybean MON 87708 × MON 89788 (MON-877Ø8-9 × MON-89788-1), Decision 2016/1216<sup>158</sup> and
- Soybean MON 87705 × MON 89788 (MON-877Ø5-6 × MON-89788-1), Decision 2016/1217<sup>159</sup>

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

Commission Implementing Decision (EU) 2016/1685 of 16 September 2016 authorised the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, and genetically modified maizes combining two or three of the events Bt11, MIR162, MIR604 and GA21, and repealing Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU (notified under document C(2016) 5746).<sup>160</sup>

#### 3.3.1 Cultivation of GMOs

Commission Directive 2015/412<sup>161</sup> amends Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. This devolves responsibility in this matter to Member States. See our previous quarterly report<sup>162</sup> for further details.

---

<sup>155</sup> <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm>

<sup>156</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1436450297142&uri=CELEX:02003R1829-20080410>

<sup>157</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1215>

<sup>158</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1216>

<sup>159</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1217>

<sup>160</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1478632817122&uri=CELEX:32016D1685>

<sup>161</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2015.068.01.0001.01.ENG](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.068.01.0001.01.ENG)

<sup>162</sup> <https://www.gov.uk/government/publications/food-and-feed-law-legislation-review-april-to-june-2015>

### 3.4 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 the European Food Safety Authority and the UK Food Standards Agency acknowledge that meat and milk from healthy clones and healthy offspring of clones is indistinguishable from, and as safe as that from, conventionally bred animals. The Committee believes that both UK and EU policy should be based on evidence, and as such does not consider that there is any scientific justification for treating the products of the healthy offspring of clones, including semen and embryos, any differently from conventionally bred animals with regard to the production of food. The Committee notes that, in past trials, some cloned progeny have not developed normally, leading to significant welfare problems and premature death.<sup>163</sup>

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.<sup>164</sup> This appears still to be the case.

### 3.5 Honey

The making and coming into force of the Honey (Wales) Regulations 2015<sup>165</sup> (SI 1507, W174) completed the updating of domestic implementation of Council Directive 2001/110/EC relating to honey<sup>166</sup>. These regulations sit alongside the Honey (Scotland) Regulations 2015 (SSI 208)<sup>167</sup>, the Honey Regulations (Northern Ireland) 2015 (SR 261)<sup>168</sup>, and the Honey Regulations (England) 2015<sup>169</sup> (SI 1348) all revoking their 2003 predecessors. The Regulations regulate the use of the names “honey”, “blossom honey”, “nectar honey”, “honeydew honey”, “comb honey”, “chunk honey” and “cut comb in honey”, “drained honey”, “extracted honey”, “pressed honey”, “filtered honey” and “baker’s honey”.

Compositional criteria and labelling are prescribed and an obligation is imposed on food authorities to enforce the Regulations. Provisions of the Food Safety Act 1990 enabling an improvement notice to be served requiring compliance with specified provisions of the Regulations are included and failure to comply with an improvement notice is an offence.

The Food Information Regulations 2014 are amended with a transitional provision in respect of food placed on the market or labelled before 24 June 2015, prohibiting an improvement notice from being served in relation to such food if it would have been compliant with the 2003 Honey Regulations.

---

<sup>163</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/524769/fangr-cloning-farm-animals-statement.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/524769/fangr-cloning-farm-animals-statement.pdf)

<sup>164</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/332618/Cloned\\_animal\\_report.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/332618/Cloned_animal_report.pdf)

<sup>165</sup> [http://www.legislation.gov.uk/wsi/2015/1507/pdfs/wsi\\_20151507\\_mi.pdf](http://www.legislation.gov.uk/wsi/2015/1507/pdfs/wsi_20151507_mi.pdf)

<sup>166</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1445979649018&uri=CELEX:02001L0110-20140623>

<sup>167</sup> <http://www.legislation.gov.uk/ssi/2015/208/contents/made>

<sup>168</sup> <http://www.legislation.gov.uk/nisr/2015/261/contents/made>

<sup>169</sup> [http://www.legislation.gov.uk/uksi/2015/1348/pdfs/uksi\\_20151348\\_en.pdf](http://www.legislation.gov.uk/uksi/2015/1348/pdfs/uksi_20151348_en.pdf)

### 3.6 Novel foods

Novel foods and novel food ingredients are regulated by Regulation (EC) No 258/97 due to be replaced on 1<sup>st</sup> January 2018 by Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods<sup>170</sup>. A Commission Q&A is available<sup>171</sup> and a list of authorisations<sup>172</sup>. 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. Public consultation on the draft guidance was open until 21 April 2016 and the guidance documents are expected to be finalised and adopted before the end of 2016.<sup>173</sup>

Commission Implementing Decision (EU) 2016/1189 of 19 July 2016 authorised the placing on the market of UV-treated milk as a novel food. The UV treatment of the pasteurised milk results in an increase in the vitamin D content of the milk. Where the UV-treated milk contains an amount of vitamin D that is considered significant in accordance with Point 2 of Part A of Annex XIII to Regulation 1169/2011 the designation for the labelling shall be accompanied by 'contains vitamin D produced by UV-treatment' or 'milk containing vitamin D resulting from UV-treatment'.<sup>174</sup>

Commission Implementing Decision (EU) 2016/1190 of 19 July 2016 authorised the placing on the market of *trans*-resveratrol as a novel food ingredient to be used in food supplements in capsule or tablet form intended for adult population only with a maximum dose of 150 mg per day without prejudice to the provisions of Directive 2002/46/EC. The metabolite *trans*-resveratrol sulfate could inhibit CYP enzymes in humans and may interact with medicines which are mainly metabolised by CYP2C9<sup>175</sup> hence the labelling of food supplements containing *trans*-resveratrol must bear a statement that people using medicines should only consume the product under medical supervision. *Trans*-resveratrol, Figure 1, a polyphenol compound found in grapes, has been investigated for its cardiovascular benefits however no valid health claim has been authorised to date. The novel food assessment relates to synthetic *trans*-resveratrol.<sup>176</sup>

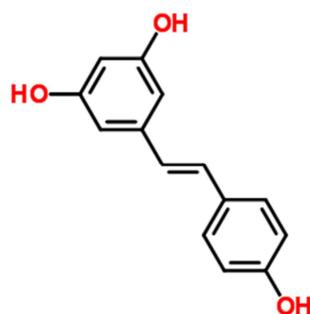


Figure 1 *Trans*-resveratrol, source Chemspider

<sup>170</sup> [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](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)

<sup>171</sup> [http://europa.eu/rapid/press-release\\_MEMO-15-5875\\_en.htm](http://europa.eu/rapid/press-release_MEMO-15-5875_en.htm)

<sup>172</sup> [http://ec.europa.eu/food/safety/novel\\_food/authorisations/list\\_authorisations/index\\_en.htm](http://ec.europa.eu/food/safety/novel_food/authorisations/list_authorisations/index_en.htm)

<sup>173</sup> [http://www.efsa.europa.eu/en/press/news/160415?mc\\_cid=e1843f434a&mc\\_eid=f1b5809dbc](http://www.efsa.europa.eu/en/press/news/160415?mc_cid=e1843f434a&mc_eid=f1b5809dbc)

<sup>174</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1189>

<sup>175</sup> EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016. Scientific opinion on the safety of synthetic *trans*-resveratrol as a novel food pursuant to Regulation (EC) No 258/97. EFSA Journal 2016;14(1):4368, 30 pp. doi:10.2903/j.efsa.2016.4368 <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4368/epdf>

<sup>176</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1190>

Commission Implementing Decision (EU) 2016/1344 of 4 August 2016 authorised the placing on the market of organic silicon (monomethylsilanetriol, Figure 2) as a novel food ingredient under Regulation (EC) No 258/97 for use as a source of silicon in food supplements.<sup>177, 178</sup>

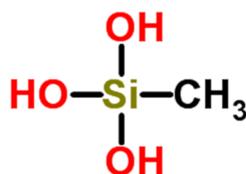


Figure 2 Monomethylsilanetriol, source *Chemspider*

### 3.7 Olive oil

Further to Regulation (EU) No 1308/2013 of 17 December 2013 that establishes a common organisation of the markets in agricultural products and in particular point (d) of the first paragraph and the second paragraph of Article 91, 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. Those methods are regularly updated in line with the work of the International Olive Council. Commission Implementing Regulation (EU) 2016/1227 of 27 July 2016 amended Regulation (EEC) No 2568/91 on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis. The revised methods for the determination of free acidity and the organoleptic assessment of virgin olive oils are set out in Regulation (EU) 2016/1227 with performance characteristics.<sup>179</sup> Commission Implementing Regulation (EU) 2016/1784 of 30 September 2016 amended Regulation 2568/91 to replace the text of the method for the determination of peroxide value<sup>180</sup>.

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.<sup>181</sup>

### 3.8 Protected names

There are three protection marks in the EU:<sup>182</sup>

- 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.<sup>183</sup>

---

<sup>177</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1344>

<sup>178</sup> EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2016. Scientific opinion on the safety of 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. EFSA Journal 2016;14(4):4436, 23 pp. doi:[10.2903/j.efsa.2016.4436](https://doi.org/10.2903/j.efsa.2016.4436)

<sup>179</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1227>

<sup>180</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1478632817122&uri=CELEX:32016R1784>

<sup>181</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016D1080>

<sup>182</sup> [http://ec.europa.eu/agriculture/quality/schemes/index\\_en.htm](http://ec.europa.eu/agriculture/quality/schemes/index_en.htm)

<sup>183</sup> <https://www.gov.uk/guidance/eu-protected-food-names-how-to-register-food-or-drink-products>

### 3.9 Consumer attitudes

See previous quarterly reports; no new centrally published information was recorded in the quarter.

### 3.10 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.<sup>184</sup>

On 1 July 2016 Commission Regulation (EU) 2016/1067 amended Annex III to Regulation (EC) No 110/2008 on geographical indications (such as *Scotch Whisky*). Pursuant to Article 20(1) of Regulation 110/2008, Member States were to submit to the Commission a technical file for each established geographical indication however 87 geographical indication files were not submitted by the deadline and have been removed from Annex III. The remaining geographical indications will be assessed but in the meantime are listed in Regulation 2016/1067.<sup>185</sup>

Commission Regulation (EC) No 2870/2000 lists and describes the reference methods for the analysis of spirit drinks. However, some methods, e.g. for the determination of volatile acidity and total sugars require attention as they have been subjected to two international validation studies. Regulation (EC) No 110/2008 lays down requirements for some categories of spirit drinks to be aged in wood and provides that others may undergo such ageing. Analysis of the principal compounds coming from wood can be helpful when considering if a sample is consistent with the definition corresponding to the relevant category of spirit drink. A method that has been collaboratively trialled has therefore been added. These changes are put into effect by Commission Implementing Regulation (EU) 2016/635 of 22 April 2016, amending the Annex to Regulation (EC) No 2870/2000.<sup>186</sup>

### 3.11 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.<sup>187, 188</sup>

### 3.12 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.<sup>189</sup>

---

<sup>184</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474277348569&uri=CELEX:02008R0110-20160705>

<sup>185</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1067>

<sup>186</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2016.108.01.0001.01.ENG&toc=OJ:L:2016:108:TOC&mc\\_cid=127fb196ca&mc\\_eid=f1b5809dbc](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.108.01.0001.01.ENG&toc=OJ:L:2016:108:TOC&mc_cid=127fb196ca&mc_eid=f1b5809dbc)

<sup>187</sup> <https://www.gov.uk/government/publications/consumer-rights-act-2015/consumer-rights-act-2015>

<sup>188</sup> <http://www.which.co.uk/consumer-rights/regulation/consumer-rights-act>

<sup>189</sup> [http://www.oecd-ilibrary.org/agriculture-and-food/international-standards-for-fruit-and-vegetables\\_19935668](http://www.oecd-ilibrary.org/agriculture-and-food/international-standards-for-fruit-and-vegetables_19935668)

## 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.<sup>190</sup>

Guidance on nutrition labelling is available on the Commission website.<sup>191</sup> Commission Regulation (EU) No 432/2012 established the list of permitted health claims and started to apply from 14 December 2012.<sup>192</sup> The EU Register of nutrition and health claims is also available<sup>193</sup> hence successive amendments to Regulation 432/2012 are not usually recorded here unless a change is made that requires further explanation.

One such case occurred in August 2016 when Commission Regulation (EU) 2016/1413<sup>194</sup> 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 4.2 below) therefore, the references to Directive 96/8/EC needed to be replaced. Regulation 1169/2011 on the provision of food information to consumers (see 3.1 above) 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.

---

<sup>190</sup> [http://ec.europa.eu/food/safety/labelling\\_nutrition/claims/refit/index\\_en.htm](http://ec.europa.eu/food/safety/labelling_nutrition/claims/refit/index_en.htm)

<sup>191</sup> [http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm)

<sup>192</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012R0432>

<sup>193</sup> [http://ec.europa.eu/food/safety/labelling\\_nutrition/claims/register/index\\_en.htm](http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/index_en.htm)

<sup>194</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1413>

Regular bulletins are available from the Department of Health on EU legislation on nutrition and health claims.<sup>195</sup>

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

Regulation (EU) No 609/2013, which came fully into effect from 20 July 2016, lays down general compositional and information requirements for the above categories of food, including infant formula and follow-on formula. The Commission adopted specific compositional and information requirements for infant formula and follow-on formula, taking into account the provisions of Directive 2006/141/EC. Infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first months of life until the introduction of appropriate complementary feeding. In order to safeguard the health of those infants, it is necessary to ensure that infant formula is the only product marketed as suitable for such use during that period. The essential composition of infant formula and follow-on formula must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data. Infant formula and follow-on formula are sophisticated products that are specially formulated for a vulnerable group of consumers. In order to ensure the safety and suitability of such products, detailed requirements are laid down on the composition of infant formula and follow-on formula, including requirements on energy value, macronutrient and micronutrient content. These requirements are based on an EFSA opinion on the essential composition of infant and follow-on formulae. Commission Delegated Regulation 2016/127<sup>196</sup> supplements Regulation 609/2013 as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. Commission Delegated Regulation 2016/128<sup>197</sup> 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.<sup>198</sup> 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, Wales and Northern Ireland introducing an improvement notice, IN, enforcement regime in which failure to comply with an IN is a criminal offence. In the English<sup>199</sup> and Welsh<sup>200</sup> 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

---

<sup>195</sup> <https://www.gov.uk/government/publications/nutritional-and-health-claims-legislation-bulletins-2015>

<sup>196</sup> [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](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)

<sup>197</sup> [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](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)

<sup>198</sup> <http://www.legislation.gov.uk/ssi/2016/190/contents/made>

<sup>199</sup> The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016

[http://www.legislation.gov.uk/uk/si/2016/688/pdfs/uksi\\_20160688\\_en.pdf](http://www.legislation.gov.uk/uk/si/2016/688/pdfs/uksi_20160688_en.pdf)

<sup>200</sup> The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016

<http://www.assembly.wales/laid%20documents/sub-ld10709/sub-ld10709-e.pdf>

Follow-on Formula (England) Regulations 2007, and their Welsh equivalent, the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009 and their Welsh equivalent.

In Northern Ireland<sup>201</sup> 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).

### 4.3 Sugar

Sugar is a topic of keen current interest and in October 2015 Public Health England published<sup>202</sup> a review of a broad range of measures to reduce the nation's excessive sugar consumption. The evidence review showed that action to reduce sugar consumption levels could include, but is not limited to, reducing:

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

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

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

The Health (Miscellaneous Provision) Act (Northern Ireland) 2016: Chapter 26<sup>203</sup>, 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.

---

<sup>201</sup> The Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016  
<http://www.legislation.gov.uk/nisr/2016/251/made>

<sup>202</sup> <https://www.gov.uk/government/news/new-evidence-review-of-measures-to-reduce-sugar-consumption>

<sup>203</sup> [http://www.legislation.gov.uk/niu/2016/26/pdfs/niu\\_20160026\\_en.pdf](http://www.legislation.gov.uk/niu/2016/26/pdfs/niu_20160026_en.pdf)

## 4.4 Food supplements

A useful summary by the Department of Health on legislation relating to the sale of food supplements is available.<sup>204</sup>

# 5 Regulation

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

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

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

Amongst the eight recommendations, the review concluded that the role of providing independent, high-level advice and challenge on the FSA's use of science should pass from the GACS to a new Science Council. This mirrors similar models in other Government departments. It is also recommended that the FSA should consult on moving the functions of the ACNFP and ACAF into a new committee, with a wider remit on innovation in the food chain. This would be established by December 2017. The SSRC will work as an expert committee of the FSA, focusing on providing advice and challenge on how the FSA can use social sciences to deliver its strategic priorities. The ACMSF and COT will retain their current structure and function.

The review reinforced the importance of ensuring that the advisory committees continue to operate to the established high standards of independence, openness and transparency, including holding open meetings and publishing papers, minutes and reports, and having access to FSA officials and the Board. Further recommendations can be viewed in the full report.<sup>205</sup>

## 5.1 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.<sup>206</sup> RDNA appears to be a useful mechanism of clarifying regulatory need and seems to be open to all stakeholders.<sup>207</sup> 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.<sup>208</sup>

---

<sup>204</sup> <https://www.gov.uk/government/publications/food-supplements-guidance-and-fags> .

<sup>205</sup> <https://www.food.gov.uk/news-updates/news/2016/15022/triennial-review-of-six-fsa-scientific-advisory-committees>

<sup>206</sup> [https://www.gov.uk/government/news/fresh-food?mc\\_cid=127fb196ca&mc\\_eid=f1b5809dbc](https://www.gov.uk/government/news/fresh-food?mc_cid=127fb196ca&mc_eid=f1b5809dbc)

<sup>207</sup> <http://rdna-tool.bis.gov.uk/>

<sup>208</sup> <http://www.regulatorsdevelopment.info/grip/food>

## 5.2 Food law prosecutions database

In November 2015 the FSA announced<sup>209</sup> the publication of a food law prosecutions database. The database<sup>210</sup> gives details of local authority food hygiene and food safety prosecutions outlining where and how food businesses have breached regulations. This data is supplied on a voluntary basis by local authority officers.

## 5.3 Food Standards Scotland

The Food (Scotland) Act 2015<sup>211</sup> established Food Standards Scotland (FSS) and describes the structure and function of this new food body in Scotland coming into operation on 1 April 2015.

## 5.4 Import controls

Commission Regulation (EC) No 669/2009 lays down rules concerning increased levels of official controls on imports of feed and food of non-animal origin when warranted by evidence of increasing threats to the food chain. The regulation is therefore periodically updated as new threats emerge or others are brought under control. Commission Implementing Regulation (EU) 2016/443 of 23 March 2016 brought in additional controls for groundnuts and derived products originating from Madagascar (aflatoxins), palm oil from Ghana (Sudan dyes), and lemons from Turkey (pesticides residues). Enhanced surveillance of aubergines and bitter melon from the Dominican Republic was discontinued.<sup>212</sup>

Commission Implementing Regulation (EU) 2016/874 of 1 June 2016 amended Implementing Regulation (EU) 2015/943 on emergency measures suspending imports of dried beans from Nigeria owing to residues of the pesticide dichlorvos. Concentrations largely exceeding the acute reference dose tentatively established by EFSA were found and the prohibition which was to apply until 30 June 2016 was extended for another three years.<sup>213</sup>

Commission Implementing Decision (EU) 2016/884 of 1 June 2016 amended Implementing Decision 2014/88/EU suspending imports from Bangladesh of foodstuffs containing or consisting of betel leaves ("Piper Betle") due to the presence of a wide range of *salmonella* by extending the suspension until 30 June 2018.<sup>214</sup>

Commission Implementing Regulation (EU) 2016/1024 of 24 June 2016 amended Regulation (EC) No 669/2009 to increase import surveillance of consignments of hazelnuts originating from Georgia for aflatoxins. As a result of improved safety entries for dried grapes from Afghanistan (for ochratoxin A) and almonds from Australia (for aflatoxins) were deleted.<sup>215</sup>

The Food Standards Agency annual reports and accounts for 2015/16 were published.<sup>216</sup>

---

<sup>209</sup> <http://www.food.gov.uk/news-updates/news/2015/14644/food-standards-agency-publishes-food-law-prosecutions-database>

<sup>210</sup> <http://www.food.gov.uk/enforcement/prosecutions>

<sup>211</sup> [http://www.legislation.gov.uk/asp/2015/1/pdfs/asp\\_20150001\\_en.pdf](http://www.legislation.gov.uk/asp/2015/1/pdfs/asp_20150001_en.pdf)

<sup>212</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1466699635302&uri=CELEX:32016R0443>

<sup>213</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2016.145.01.0018.01.ENG&toc=OJ:L:2016:145:TOC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.145.01.0018.01.ENG&toc=OJ:L:2016:145:TOC)

<sup>214</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2016.146.01.0029.01.ENG&toc=OJ:L:2016:146:TOC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.146.01.0029.01.ENG&toc=OJ:L:2016:146:TOC)

<sup>215</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1024&rid=214>

<sup>216</sup> <https://www.food.gov.uk/sites/default/files/fsa-westminster-accounts-2015-2016.pdf> and [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/540636/fsa-annual-report-and-consolidated-accounts-2015-to-2016.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/540636/fsa-annual-report-and-consolidated-accounts-2015-to-2016.pdf)

## 5.5 Local authority enforcement activity

No centrally published new updates were published in the quarter. We remain open to including in this review any updates communicated by individual local authorities to the author. However see section 5.2 for the food law prosecutions database which is based on local authority activity.

## 5.6 Multi-Annual National Control Plan

No centrally published new updates were published in the quarter.

## 5.7 Food Law Code of Practice

No centrally published new updates were published in the quarter.

## 5.8 National sampling priorities for food

The FSA has been working with UK local authorities since 2003 to support Enforcement Authority risk-based sampling and surveillance of food sold in the UK, whether it is imported or produced in the EU or UK.<sup>217</sup> The FSA has invited<sup>218</sup> recommendations for priorities for the 2016-17 National Coordinated Sampling Programme which were published in September 2016<sup>219</sup>. The FSA in Northern Ireland published its eighth food surveillance sampling report.<sup>220</sup>

## 5.9 Community Reference Laboratories

See section 6.2, 'Feed Additives'.

# 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

---

<sup>217</sup> <https://www.food.gov.uk/enforcement/sampling/samplingandsurveillance>

<sup>218</sup> <https://www.food.gov.uk/news-updates/help-shape-our-policies/priorities-for-the-2016-17-national-coordinated-sampling-programme>

<sup>219</sup> <https://www.food.gov.uk/sites/default/files/food-sampling-guidance-2016-17.pdf>

<sup>220</sup> <https://www.food.gov.uk/northern-ireland/news-updates/news/2015/14469/northern-ireland-food-surveillance-sampling-report-published>

methods of analysis where the sampling has not been carried out in the course of official controls and making it an offence to tamper or otherwise interfere with a sample.

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

The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015<sup>221</sup> (SI 255) amended the Official Feed and Food Controls (England) Regulations 2009 (SI 3255) and revoked the Genetically Modified Animal Feed (England) Regulations 2004 (SI 2334), the Feed (Corn Gluten Feed and Brewers Grains) (Emergency Control) (England) (Revocation) Regulations 2007 (SI 3007) and the Animal Feed (England) Regulations 2010 (SI 2503), other than regulations 1, 2 and 14. These Regulations give effect to:

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

Similar regulations were made in Northern Ireland to make provision as to administration generally in relation to feed law, in particular so as to give effect to Regulation (EC) No. 882/2004. These were the Animal Feed (Composition, Marketing and Use) (Northern Ireland) Regulations 2016<sup>222</sup> (SR 4) amending:

- The Official Feed and Food Controls (Northern Ireland) Regulations 2009 (SR 427) and The Animal Feed (Hygiene, Sampling etc. and Enforcement) Regulations (Northern Ireland) 2016<sup>223</sup> (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);

---

<sup>221</sup> [http://www.legislation.gov.uk/uksi/2015/255/pdfs/ukxi\\_20150255\\_en.pdf](http://www.legislation.gov.uk/uksi/2015/255/pdfs/ukxi_20150255_en.pdf)

<sup>222</sup> [http://www.legislation.gov.uk/nisr/2016/4/pdfs/nisr\\_20160004\\_en.pdf](http://www.legislation.gov.uk/nisr/2016/4/pdfs/nisr_20160004_en.pdf)

<sup>223</sup> [http://www.legislation.gov.uk/nisr/2016/5/pdfs/nisr\\_20160005\\_en.pdf](http://www.legislation.gov.uk/nisr/2016/5/pdfs/nisr_20160005_en.pdf)

- Regulations 4, 5, 6, 20, 21, and 22 and Schedule 1 of the Feed (Sampling and Analysis and Specified Undesirable Substances) Regulations (Northern Ireland) 2010 (SR 323);
- The Feed (Hygiene and Enforcement) and the Animal Feed (Amendment) Regulations (Northern Ireland) 2013 (SR 294).

### 6.1.1 Mycotoxin recommended limits

Commission Recommendation (EU) 2016/1319<sup>224</sup> 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<sup>-1</sup> (from recent evidence including from EFSA) appears too high and is reduced to 2 mg kg<sup>-1</sup>. Guideline levels for zearalenone and ochratoxin A in feed for cats and dogs are established at 0.2 mg kg<sup>-1</sup> and 0.01 mg kg<sup>-1</sup> respectively.

### 6.1.2 Dioxin testing

Regulation (EC) No 183/2005 of the European Parliament and of the Council lays down general rules on feed hygiene and processing conditions. Commission Regulation 2015/1905<sup>225</sup> amended Annex II to as regards the dioxin testing of oils, fats and derived products. The amendment made the following clarifications:

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

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

<sup>224</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016H1319>

<sup>225</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2015.278.01.0005.01.ENG](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.278.01.0005.01.ENG)

### 6.1.3 Nickel in feed

See section 2.3.5 – 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.<sup>226</sup>

## 6.2 Feed additives

Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. A register of feed additives is available.<sup>227</sup>

In May 2016 the EFSA Panel on Additives and Products or Substances used in Animal Feed, FEEDAP, reviewed a series of guidance documents intended to help applicants in their preparation of technical dossiers, listed those that remain relevant and identified those that will need to be revised.<sup>228</sup>

### 6.2.1 Community and National Reference Laboratories

Regulation (EC) No 1831/2003 deals with application for, and authorisation of, feed additives in animal nutrition with detailed rules in Regulation (EC) No 1831/2003 including the duties and tasks of the Community Reference Laboratory (CRL). In October 2015 Commission Implementing Regulation 2015/1761<sup>229</sup> amended Regulation 378/2005 as regards the Community Reference Laboratory reports, fees and the feed additive national reference laboratories, including LGC, listed in Annex II thereto.

## 6.3 Fertilisers

Legislation on fertilisers is highly technical and treated here but briefly. The overarching European measure is Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003.<sup>230</sup> 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.<sup>231</sup>

# 7 Acknowledgement

Editorial assistance from Elena Sanchez and Vicki Barwick is gratefully acknowledged. Funding from the Department for Business, Energy & Industrial Strategy under the Government Chemist Programme for work carried out in this project is gratefully acknowledged.

---

<sup>226</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1471533458929&uri=CELEX:32016H1110>

<sup>227</sup> [http://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register/index\\_en.htm](http://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register/index_en.htm)

<sup>228</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/4473>

<sup>229</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2015.257.01.0030.01.ENG](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.257.01.0030.01.ENG)

<sup>230</sup> 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>

<sup>231</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474057348374&uri=CELEX:32016R1618>