Government Chemist legislation

Annual statement of statutory scope

January 2016

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1. Summary

The Government Chemist currently has specific statutory functions under seven Acts of the UK Parliament. This statement is an updated record of legislation that is now in force and names the Government Chemist, or relates to the way in which the Government Chemist needs to exercise these functions. For ease of reference, Table 1 lists the main changes to the statement since the last update in January 2015.

Table 1: Main changes to this paper since the January 2015 version

Legislation	Section	Change
Food	3.1.5 3.1.7	Country of Origin of Meats New Natural Mineral Water, Spring Water and Bottled Drinking Water for the 4 home countries
Agriculture	-	The Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015
Medicines	-	
Farm and garden chemicals	-	
Hydrocarbon oil duties	4.1	Amendment to Hydrocarbon Oils marking regulations to introduce new Common fiscal UK marker.
Poisons	-	
Merchant shipping	-	
Framework	6.2.3	New Food (Scotland) Act 2015

There were few significant changes in 2015, although there were a large number of more minor regulations published. This continues to reflect the completion of a period of major review of food law by 2012 and both the European Commission's and the current government's policy to reduce the regulatory burden, and also reflect the rationalization of regulations in similar areas which is line with the aim of simplifying regulation.

2. Introduction

This paper states the legislative scope of the Government Chemist statutory function. It amends the statement prepared in January 2015[1], and comprises:

[1] Nick Boley, *Government Chemist legislation: annual statement of statutory scope*. January 2015, report number LGC/RT/2015/388, https://www.gov.uk/government/publications/government-chemist-annual-statement-of-statutory-scope-2015

- A record of primary and secondary legislation currently in force that names the Government Chemist or his Laboratory
- A context that helps to scope or illustrate the practical implications[2].

2.1 Inputs

This year we continued our daily review of newly published legislation through:

- The UK Daily List[3] published by TSO
- The Official Journal of the European Union (OJ)[4].

This year we made a note of all newly-published legislation and incorporated it into this document on a rolling basis. To ensure that nothing had been missed we also conducted an orderly annual review just before the final revision of this paper.

Online searches up to 23 December 2015 confirmed that this paper captures the current situation with regard to 'Government Chemist' in legislation. The official resource available to us for this purpose is the National Archives Legislation website[5] which combined the former Office of Public Sector Information (OPSI) website and the UK Statute Law Database prior to the last revision.

In seeking to understand and advise on the implications of any changes, we believe it is important to be able to review relevant legislation exactly as it is now in force, i.e. the original text combined with subsequent amendments. At EU level, an effective search facility is in place for this 'consolidated' legislation[6]. The Statute Law Database, and, drawing upon it, the OPSI website, provides access to primary legislation in revised form. We also rely on a commercially available resource to review and interpret national secondary legislation in its latest form[7].

Foresight of possible changes to the statutory scope and operational context for the Government Chemist is clearly desirable, and is one of the drivers for our horizon scanning activity and careful consideration of consultation documents on relevant proposed legislation changes. While we continuously seek to improve this aspect of horizon scanning on our own initiative, access to or collaboration with any relevant central government facility or departmental resource could certainly help. We continue to welcome suggestions

[2] For further context see the Government Chemist website: http://www.governmentchemist.org.uk

[3] http://www.tso.co.uk/daily_list/issues.htm

[4] http://eur-lex.europa.eu/JOIndex.do?ihmlang=en

[5] http://www.legislation.gov.uk

[6] http://eur-lex.europa.eu/REACH_consolidated.do

[7] LexisNexis Butterworths.

2.2 Document outline

We have classified the legislation according to the three categories of activity that the Government Chemist is required to carry out under statute:

- Referee analysis (impartial analysis to help resolve disputes relating to test results obtained on behalf of two independent parties)
- Authorised analysis
- Expert advice[8].

We have listed the references in statute that help to frame the status, overall character and territorial extent of the office of Government Chemist in the final section of this paper.

3. Referee analysis

The following Acts of Parliament, or regulations made under them, name the Government Chemist, and assign a function commonly called referee analysis:

- Food Safety Act 1990
- Agriculture Act 1970
- Medicines Act 1968, as amended by the Human Medicines Regulations 2012
- Farm and Garden Chemicals Act 1967.

We are not aware of any legal definition of the referee analyst function. It is often regarded as expert analysis and interpretation by an independent third party to help avoid or resolve a dispute arising from two earlier sets of results, which do not agree and have been obtained on behalf of an enforcement authority and a trader respectively.

The following EU legislation and official documents allude to referee analysis, showing that the Community acknowledges the exercising of this function:

- Recommendation 2004/787/EC on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003 (see sections I.5 and II(g))
- Directive 2005/7/EC amending Directive 2002/70/EC establishing requirements for the determination of levels of dioxins and dioxin-like PCBs in feedingstuffs (see Annex point (1))
- Regulation (EC) No 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (see Annex I point A.3.6, and Annex II point 3 and 4.4)
- Regulation (EC) No 1882/2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs (see Annex point D.4)

[8] The Government Chemist also has a wider advisory function, relating more to the scope of expertise which it represents than to any particular act of Parliament. The wider advisory function is defined in the Government Chemist Agreement between LGC and the Secretary of State.

- Regulation (EC) No 1883/2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs (see Annex I point 5)
- Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs (see Annex points B.1.6 and C.2.4)
- Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (see Annex V point B.1.2).

See also 'Relationship with official controls legislation, 3.1.4, below.

Other legislation, for example Regulation (EC) No 273/2008 *laying down detailed rules for the application of Council Regulation (EC) No 1255/1999 as regards methods for the analysis and quality evaluation of milk and milk products* (see Annex XXI), foresees a requirement for science-based dispute resolution without alluding explicitly to a referee analyst. Moreover, the *Guidance document for competent authorities for the control of compliance with EU legislation on aflatoxins*[9] explains in detail how to take samples for 'enforcement, defence and reference'.

There are wider demands and opportunities for sound science to resolve disputes - for example, between two traders, or in relation to emerging legislation. In principle, the Government Chemist's wider advisory function could help to clarify and prioritise requirements. Our long-standing scientific and operational synergies with the UK National Measurement System are in keeping with a dispute resolution function that responds to developments across UK industry.[10]

3.1 Food Safety Act 1990

3.1.1 Context

The Government Chemist typically receives a continual stream of casework referrals under this Act, each of which requires intensive investigation and, on occasion, underpinning research or method development. The circumstances, products and determinands vary widely. Examples of casework include:

- Food safety – alleged contamination of food by mycotoxins or excess migration of formaldehyde from food contact materials
- Consumer choice and fraud - problems around alleged misdescriptions involving the species of meat, quantitative declarations of, usually, high value ingredients (QUID), alcoholic strength or presence of GMO ingredients
- Investigation of emerging and scientifically challenging issues such as botanical, functional and allergenic constituents of food products
- Generating evidence about the application of regulated processes such as irradiation.

The Government Chemist's referee function is a demand-led service with little control over the nature or timing of casework presented for investigation. Requests for analysis often require the development, at short notice, of an

[9] Revision 1: http://ec.europa.eu/food/food/chemicalsafety/contaminants/comm_dec_2006_504guidance_en.pdf

[10] Questions of cost and value will clearly arise, but can be addressed on a case-by-case basis. They are subordinate to the main issue of who is most suitable to resolve particular categories of dispute by sound measurement and scientific interpretation.

opinion on issues that present serious challenges to modern analytical science. As food technology develops, and related risks are either perceived or assessed, legislators often respond by requiring measurements that challenge the technical capabilities of analytical laboratories. The Government Chemist must be in a position to address the measurement issues that may arise.

Food law in the UK is criminal law with the associated stringent burden of proof - 'beyond reasonable doubt'. Prosecutions are usually brought under a wide range of secondary legislation to which common enforcement provisions, including the referee analyst function, apply. Increasingly, the interpretation of results of analysis and their associated measurement uncertainty in this forensic context requires skilled resource equal to that of obtaining the measurements themselves.

3.1.2 Principal references to the Government Chemist

(a) In the Act

In general, the geographic scope of the Food Safety Act 1990 is Great Britain. Sections 29 to 31 relate to sampling and analysis[11]. Section 31(2) of the Act names the Government Chemist (Box 1). It states that regulations made under Section 31(1) may specify the circumstances in which samples can be referred to the Government Chemist for analysis or examination.

Box 1: Food Safety Act 1990

> 31.—(1) The Ministers may by regulations make provision for supplementing or modifying the provisions of sections 29 and 30 above.
>
> (2) Without prejudice to the generality of subsection (1) above, regulations under that subsection may make provision with respect to—
>
> ... (h) the circumstances in which samples, or parts of samples, are to be or may be submitted for analysis or examination—
>
> (i) to the Government Chemist, or to such other food analyst or examiner as he may direct; or
>
> (ii) to a person determined by or under the regulations.

(b) In the Sampling and Qualifications (S&Q) Regulations

The regulations referred to in Section 31(2) of the 1990 Act were made as the Food Safety (Sampling and Qualifications) Regulations 1990 (SI 2463), now superseded by the Food Safety (Sampling and Qualifications) (England) Regulations 2013 (SI 264)[12] , the Food Safety (Sampling and Qualifications) (Scotland) Regulations 2013 (S.S.I. 84)[13] and the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013 (S.I. 479, W. 55).[14]

These new S&Q Regulations make two references to the Government Chemist:

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[11] The Government Chemist is mentioned in the FSA *Practical sampling guidance for food standards and feeding stuffs*, May 2004, Part 2, http://www.food.gov.uk/multimedia/pdfs/samplingguidancepart2.pdf. The guidance explains the need to divide 'formal' samples into three, the third part being retained for possible submission to the Government Chemist (page 14); discusses good practice for storing the retained part (page 22); and highlights the need to produce it at the start of any court hearing (page 25).

[12] http://www.legislation.gov.uk/uksi/2013/264/contents/made

[13] http://www.legislation.gov.uk/ssi/2013/84/contents/made

[14] http://www.legislation.gov.uk/wsi/2013/479/regulation/1/made

- Regulation 8 makes the procedure for submission of referee samples to the Government Chemist available across the scope of the Act (Box 2). This includes secondary legislation that makes no explicit mention of the Government Chemist. According to Regulation 8, the sample is submitted to the Government Chemist for analysis, not examination[15]
- Under Regulation 4, Schedule 2 Part 2 names the Laboratory of the Government Chemist as the first of 13 categories of laboratories in which a scientist may gain suitable experience for the official food control post of food examiner (provided the experience consists of microbiological examination of food).

Box 2: Food Safety (Sampling and Qualifications) Regulations 2013

8 An authorised officer —

(a) may of the officer's own volition;

(b) shall if requested by the prosecutor (if a person other than the authorised officer);

(c) shall if the court so orders; or

(d) shall, subject to paragraph (6), if requested by the person accused,

send the retained part of the sample to the Government Chemist for analysis.

4.—(1) A person shall be qualified to be a food examiner if that person ... has carried out examination of food over a period or periods amounting in aggregate to at least 3 years in one or more of the laboratories listed in Part 2 of that Schedule.

PART 2

LIST OF LABORATORIES

1. The Laboratory of the Government Chemist ...

3.1.3 Northern Ireland

The following legislation naming the Government Chemist establishes requirements broadly equivalent to those under the 1990 Act as regards the general nature and chemical scope of referee analysis in Northern Ireland:

- The Food (Northern Ireland) Order 1989 (SI 846, NI 6) Article 56
- The Food Safety (Northern Ireland) Order 1991 (SI 762, NI 7) Article 32. The administrative provisions relating to enforcement differ in some respects from those in Great Britain.

The Food Safety (Sampling and Qualifications) Regulations (Northern Ireland) 2013 (SR 66)[16] refer to the Government Chemist and the Laboratory of the Government Chemist using the same form of words as the 2013 regulations for both England (and Wales), and Scotland (Box 2).

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[15] Experience pre-dating the Food Safety Act 1990 had shown that a court might expect an expert witness to show that evidence scientifically merits the term analysis. Section 53 (General interpretation) of the Act states:
‘ “analysis” includes microbiological assay and any technique for establishing the composition of food, and “analyse” shall be construed accordingly‘
This broad definition includes microbiological assay using a micro-organism as a reagent, such as in determinations of vitamins and antibiotics. Experience has shown that microscopy also falls within its scope. Under Section 28 of the Act, the term 'examination' is reserved specifically for microbiological examination. There is a reference to submission for examination in Section 31(2)(h) of the Act, but as the Government Chemist is not appointed to carry out examination by regulations under the Act, that reference defaults to another specified person in accordance with Section 31(2)(h)(ii).

[16] http://www.legislation.gov.uk/nisr/2013/66/pdfs/nisr_20130066_en.pdf

Exchanges with officials in Northern Ireland have clarified respective roles:

- The Chief Scientist at the Agri-Food and Biosciences Institute (AFBI) referees agricultural cases in Northern Ireland in the capacity of Chief Agricultural Analyst, and acts as Government Chemist for feed samples originally procured under legislation enacted by the Department of Agriculture and Rural Development (DARD). There is no currently no member of staff at AFBI with the title of Chief Scientist; enquiries go through DARD at present.
- The UK Government Chemist is referee analyst for cases arising under food legislation, either UK-wide or its Northern Ireland equivalent.

3.1.4 Relationship with official controls legislation

Underpinning provision

Regulation (EC) No 882/2004 *on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules* (the Official Controls Regulation) provides a harmonised framework for the practical implementation of measures aiming to manage risks, guarantee fair practices in feed and food trade and protect consumer interests, including through labelling and other information. This framework works alongside any more specific EU legislation that may apply.

In Regulation 882/2004, Title II (Official controls by Member States), Chapter III relates to sampling and analysis. Within Chapter III, Article 11(5) states:

'The competent authorities shall establish adequate procedures in order to guarantee the right of feed and food business operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion, without prejudice to the obligation of competent authorities to take prompt action in case of emergency.' A consultation is currently underway regarding the revision of this Regulation, and a revised Regulation was expected to be published during the first half of 2014, but has yet to appear.

Recent updates to UK legislation provide that, as one way of exercising this EU-wide right to a supplementary expert opinion, a defendant can initiate referral of the retained part of a sample to the Government Chemist[17]. More generally, the S&Q Regulations as originally made in 1990, required agreement between the authorised officer and the owner for the submission of a sample to the Government Chemist and because the underpinning EU provision is less restrictive, consent was unlikely to be withheld[18]. The current S&Q Regulations (regulation 8) have removed the requirement for agreement between the authorised officer and the owner for the submission of a referee sample.

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[17] Where this right has been incorporated into national law, the Government Chemist function is described as secondary analysis. The effect is that a trader can decide not carry out a defence analysis, and simply request that the referee portion of the sample is sent to the Government Chemist. The FSA Contaminants Branch has advised that the Agency will not be encouraging traders and authorised officers to send the retained portion of a sample to the Government Chemist for analysis before results are available from the public analyst sample and trader's portion. Notices provided by authorised officers will indicate that traders have the option to request that the referee sample is analysed when an adverse result from the public analyst sample has been obtained. In practice, the Government Chemist has experienced an increased workload associated with the right to a supplementary expert opinion established in EU law. To encourage a balanced, scientifically informed choice between secondary and referee analysis, we request evidence of a dispute by some means (e.g. a compliant pre-export certificate for imported food disputes) and the corresponding fee structure has been amended in consultation with the Government Chemist Advisory Group (now the Government Chemist Working Group). This issue will be kept under review.

[18] "Guidance for food traders on how to submit a sample to the Government Chemist for supplementary expert opinion." https://www.gov.uk/guidance/submit-a-supplementary-expert-opinion-sample

Commission Regulation (EU) 51/2013 amends Regulation (EU) 152/2009 regarding methods of analysis for the determination of constituents of animal origin in feedingstuffs, which are prohibited as they may contribute to the spread of transmissible spongiform Encephalopathies (TSEs). A new method, based upon polymerase chain reaction (PCR) has been validated by the EU reference laboratory and is now an official method. The method is reproduced in full in Annex VI of the Regulation[19]. This is linked to the publication of Commission Regulation (EU) 56/2013 which amends Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform Encephalopathies[20] and refers to the method quoted above.

Commission Regulation 630/2013[21] amends Regulation (EC) 999/2001 regarding arrangements for the sampling and testing of animals for transmissible spongiform Encephalopathies (TSEs), including the action to be taken when a case is suspected.

Commission Implementing Regulation 925/2013[22] amends Annex I to Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin.

Commission Implementing Regulation 1355/2013[23] amends Annex I to Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin.

Commission Implementing Regulation 1021/2014[24] amends Annex I to Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin.

Commission Implementing Decision 2014/745/EU[25] amends Decision 98/536/EC as regards the list of national reference laboratories, with specific regards to the monitoring of certain substances and residues thereof in live animals and animal products.

Commission Implementing Regulation 1295/2014[26] amends Annex I to Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin.

Commission Implementing Regulation 2015/525[27] amends Annex I to Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin.

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[19] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:020:0033:0043:EN:PDF

[20] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:021:0003:0016:EN:PDF

[21] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:179:0060:0083:EN:PDF

[22] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:254:0012:0019:EN:PDF

[23] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:341:0035:0042:EN:PDF

[24] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.283.01.0032.01.ENG

[25] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.308.01.0104.01.ENG

[26] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.349.01.0033.01.ENG

[27] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.084.01.0023.01.ENG

Commission Implementing Regulation 2015/1607[28] amends Annex I to Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin.

Commission Regulation 2015/1905[29] amends Annex II to Regulation (EC) No 183/2005 of the European Parliament and of the Council as regards the dioxin testing of oils, fats and products derived thereof.

Generic and specific national application of Regulation 882/2004

For each of the UK home countries[30], the Official Feed and Food Controls Regulations transpose Regulation 882/2004.[31] When updates are required, it is usual to make new regulations that revoke their predecessors. The current regulations are:

- The Official Feed and Food Controls (England) Regulations 2009 (SI 3255), revoking SI 2007/3185
- The Official Feed and Food Controls (Scotland) Regulations 2009 (SSI 446), revoking SSI 2007/522[32], as amended by the Food (Miscellaneous Amendments) (Scotland) Regulations 2013[33] and the Food Hygiene and Official Feed and Food Controls (Scotland) Amendment Regulations 2014[34].
- The Official Feed and Food Controls Regulations (Northern Ireland) 2009 (SR 427), revoking SR 2007/482
- The Official Feed and Food Controls (Wales) Regulations 2009 (SI 3376, W298), revoking SI 2007/3294 (W290).[35]

In addition, legislation covering food safety and hygiene has been enacted which complements the above legislation:

- The Food Safety and Hygiene (England) Regulations 2013[36] (SI 2996), revoking revoke and re-enacting with some minor changes the Food Hygiene (England) Regulations 2006 (S.I. 2006/14) and certain provisions of the General Food Regulations 2004 (S.I. 2004/3279) as they apply in relation to England. Similar legislation has been enacted in Northern Ireland with the Food Safety, Food Hygiene and Official Controls (Sprouting Seeds and Miscellaneous Amendments) Regulations

[28] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.249.01.0007.01.ENG

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

[30] This term is used to mean England, Scotland, Wales, and Northern Ireland.

[31] A second set of regulations in each of the UK home countries enforces Regulation 882/2004 in relation to animal health and welfare rules, and feed and food law excluded from the Official Feed and Food Controls Regulations - for example, the Official Controls (Animals, Feed and Food) (England) Regulations 2006 (SI 3472). These do not entail a Government Chemist function by reference to the S&Q Regulations.

[32] The Official Feed and Food Controls (Scotland) Regulations 2010 (SSI 5) corrected defects in SSI 2009/446, including an internal reference to the regulation that covers sampling.

[33] http://www.legislation.gov.uk/ssi/2013/336/pdfs/ssi_20130336_en.pdf

[34] http://www.legislation.gov.uk/ssi/2014/213/contents/made

[35] The 2009 regulations commenced provision for the enforcement of Regulation (EC) No 669/2009 *implementing Regulation (EC) No. 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin.*

[36] http://www.legislation.gov.uk/uksi/2013/2996/pdfs/uksi_20132996_en.pdf

(Northern Ireland) 2013[37], in Scotland with the Food Safety, Food Hygiene and Official Controls (Sprouting Seeds and Miscellaneous Amendments) Regulations (Scotland) 2013[38], and the Food (Miscellaneous Amendments) (Scotland) Regulations 2013[39], and in Wales with the Food (Miscellaneous Amendments) (Wales) Regulations 2013 (S.I. 3049/2013, W.308)[40].

Sampling and analysis is covered by a series of regulations covering sampling, analysis and undesirable substances in the UK home countries:

- The Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010 (SI 2010 No. 2280)[41]
- The Feed (Sampling and Analysis and Specified Undesirable Substances) (Wales) Regulations 2010 (SI 2010 No. 2287)[42]
- The Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) Regulations 2010 (SSI 2010 No. 354)[43]
- The Feed (Sampling and Analysis and Specified Undesirable Substances) (Northern Ireland) Regulations 2010 (SR 2010 No. 323)[44]

Labelling and information is now covered by the new Food Information Regulations (SI 2014 No 1855)[45] which largely replaces the Food Labelling Regulations 1996 (SSI1996 No 1499)[46] and subsequent amendments, and implements Regulation (EU) No 1169/2011[47] of the European Parliament and of the Council, as amended. These regulations came into force on 13 December 2014. In Northern Ireland, the Food Information Regulations (Northern Ireland) 2014 (SR 2014 No 223)[48] enact this legislation. In Wales, the Food Information Regulations (Wales) 2014 (SI 2014 No 2303, W227)[49] enact this legislation and in Scotland the Food Information Regulations (Scotland) 2014 (SSI 312)[50] enact this legislation. This latter has been amended by the Food Information (Miscellaneous Amendments) (Scotland) Regulations 2015 (SSI 410)[51]

The Official Feed and Food Controls (England) Regulations 2009 and the Food Safety and Hygiene (England) Regulations 2013 have been amended by the Official Feed and Food Controls (England) and the Food Safety and Hygiene (England) (Amendment) Regulations 2014[52] (SI 2014 No 2748). The major changes conferred by these amendments include implementation of both

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[37] http://www.legislation.gov.uk/nisr/2013/291/pdfs/nisr_20130291_en.pdf

[38] http://www.legislation.gov.uk/ssi/2013/333/pdfs/ssi_20130333_en.pdf

[39] http://www.legislation.gov.uk/ssi/2013/336/pdfs/ssi_20130336_en.pdf

[40] http://www.legislation.gov.uk/wsi/2013/3049/pdfs/wsi_20133049_mi.pdf

[41] http://www.legislation.gov.uk/uksi/2010/2280/contents/made

[42] http://www.legislation.gov.uk/wsi/2010/2287/contents/made

[43] http://www.legislation.gov.uk/ssi/2010/354/contents/made

[44] http://www.legislation.gov.uk/nisr/2010/323/contents/made

[45] http://www.legislation.gov.uk/uksi/2014/1855/pdfs/uksi_20141855_en.pdf

[46] http://www.legislation.gov.uk/uksi/1996/1499/made/data.pdf

[47] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF

[48] http://www.legislation.gov.uk/nisr/2014/223/pdfs/nisr_20140223_en.pdf

[49] http://www.legislation.gov.uk/wsi/2014/2303/pdfs/wsi_20142303_mi.pdf

[50] http://www.legislation.gov.uk/ssi/2014/312/pdfs/ssi_20140312_en.pdf

[51] http://www.legislation.gov.uk/ssi/2015/410/pdfs/ssi_20150410_en.pdf

[52] http://www.legislation.gov.uk/uksi/2014/2748/pdfs/uksi_20142748_en.pdf

Commission Regulation (EU) No. 211/2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts, and Commission Regulation (EU) No. 579/2014(e) granting derogation from certain provisions of Annex II to Regulation (EC) No. 852/2004 of the European Parliament and of the Council as regards the transport of liquid oils and fats by sea. Similar amendments have been enacted in Northern Ireland with the Food Hygiene and Official Feed and Food Controls (Amendment) Regulations (Northern Ireland) 2014[53] (SR 286/2014) which amend the Food Hygiene Regulations (Northern Ireland) 2006 and the Official Feed and Food Controls Regulations (Northern Ireland) 2009. The Official Feed and Food Controls (Wales) Regulations 2009 have been similarly amended by the Official Feed and Food Controls (Wales) (Amendment) Regulations 2014[54] (SI 2714/2014, W271), which is concerned solely with certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts.

The Official Feed and Food Controls (England) Regulations 2009 have also been amended, in England, by The Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015.

The Products Containing Meat etc. (England) Regulations 2014 (SI 3001/2014)[55] revokes the Meat Products (England) Regulations 2003 (SI 2075/2003), the Meat Products (England) (Amendment) Regulations 2008 (SI 517/2008), regulation 18(4) of the Food Additives (England) Regulations 2009 (SI 3238/2009) and the entry relating to the Meat Products (England) Regulations 2003 in the table in Part 2 of the Schedule to the Treaty of Lisbon (Changes in Terminology or Numbering) Order 2012 (SI 1809/2012). Similar Regulations have been enacted in Scotland with the Products Containing Meat etc. Regulations (Scotland) Regulations 2014 (SSI 289/2014)[56] 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[57] (SR 285/2014). These regulations lay down definitions and descriptions of meat products presented for sale directly to the consumer.

The Fish Labelling (Amendment) Regulations 2014[58] which amend the Fish Labelling Regulations 2013 (S.I. 2013/1768) to provide for the enforcement of the consumer information requirements in Chapter IV of Regulation (EC) No. 1379/2013 of the European Parliament and of the Council on the common organisation of the markets in fishery and aquaculture products. This is implemented in Northern Ireland by the Fish Labelling (Amendment) (Northern Ireland) Regulations 2014[59]. In Scotland the Fish Labelling (Scotland) Regulations 2013 (SSI 256) are amended by the Fish Labelling (Scotland) Amendment Regulations 2015[60].

The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015[61] revoke the current

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[53] http://www.legislation.gov.uk/nisr/2014/286/pdfs/nisr_20140286_en.pdf

[54] http://www.legislation.gov.uk/wsi/2014/2714/pdfs/wsi_20142714_mi.pdf

[55] http://www.legislation.gov.uk/uksi/2014/3001/pdfs/uksi_20143001_en.pdf

[56] http://www.legislation.gov.uk/ssi/2014/289/pdfs/ssi_20140289_en.pdf

[57] http://www.legislation.gov.uk/nisr/2014/285/pdfs/nisr_20140285_en.pdf

[58] http://www.legislation.gov.uk/uksi/2014/3104/pdfs/uksi_20143104_en.pdf

[59] http://www.legislation.gov.uk/nisr/2014/287/pdfs/nisr_20140287_en.pdf

[60] http://www.legislation.gov.uk/ssi/2015/48/pdfs/ssi_20150048_en.pdf

[61] http://www.legislation.gov.uk/uksi/2015/787/pdfs/uksi_20150787_en.pdf

statutory instruments and consolidate their provisions. The Regulations implement Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists(a) and Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products(b) and provide for the execution and enforcement of Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin and Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

Generically, these national regulations formalise the requirement for the UK to abide by Regulation 882/2004. In relation to a specific category of samples - feed and food of non-animal origin from third countries (i.e. those outside the EU)[62] – the national regulations also serve to illustrate how the Government Chemist referee function is commonly applied by secondary legislation under the 1990 Act. Taking SI 2009/3255 as an example, Part 3 Regulation 38(10) applies the S&Q Regulations to a sample procured by an authorised officer of a food authority under those regulations 'as if it were a sample procured by an authorised officer under section 29 of the Act'. This is a legal shorthand adopting the common enforcement provisions under the Act, including the Government Chemist referee function. The term 'procured' is used in Regulation 38(10) to cover both purchased samples and those taken without payment.

Please note that Regulation 882/2004 is currently undergoing revision and a consultation has been issued to interested parties.

Commission Implementing Regulation 2015/1761[63] amends Commission Regulation (EC) No 378/2005 as regards the Community Reference Laboratory reports, fees and the laboratories listed in Annex II thereto.

Commission Directive 2015/1787[64] amends 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.

Commission Implementing Regulation 2015/1820[65] amends Regulation (EU) No 37/2010 as regards the substance 'Diethylene glycol monoethyl ether'. This extends the permitted use of this substance to poultry.

Commission Delegated Regulation 2015/1830[66] amends Regulation (EEC) No 2568/91 on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis, covering both fatty acid analysis and measurement of component plant sterols.

Commission Implementing Regulation 2015/1833[67] amends Regulation (EEC) No 2568/91 on the characteristics of olive oil and olive-residue oil and on the relevant

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[62] EU legislation is evolving rapidly in this area. Regulation (EU) No 878/2010 amended Annex I of Regulation 669/2009 to set the frequencies of checks for aflatoxins, heavy metals, pesticides, ochratoxin A, salmonella, and Sudan dyes. Regulation (EU) No 1099/2010 then replaced the whole of Annex I, adjusting control frequencies up and down in the light of intelligence from RASFF (Rapid Alert System for Food and Feed), FVO (Food and Veterinary Office) inspections, and Member State quarterly reports.

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

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

[65] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.265.01.0001.01.ENG

[66] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.266.01.0009.01.ENG

[67] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.266.01.0029.01.ENG

methods of analysis. This lays down detailed methods of analysis to be used for identification and classification of olive oils.

Commission Implementing Regulation 2015/2062[68] amends Regulation (EU) No 37/2010 as regards the substance 'sisapronil'. The MRLs for bovine and caprine species are 100 µg/kg for muscle, 2000 µg/kg for fat, 200 µg/kg for liver and 100 µg/kg for kidney.

Regulation 2015/2283 of the European Parliament and of the Council[69] amends Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 regarding novel foods.

Regulation 2015/2284 of the European Parliament and of the Council[70] repeals Council Directive 76/621/EEC relating to the fixing of the maximum level of erucic acid in oils and fats and Council Regulation (EC) No 320/2006 establishing a temporary scheme for the restructuring of the sugar industry.

Amendments

Commission Implementing Regulation 2015/394[71] amends the Annex to Regulation (EU) No 37/2010 as regards the substance 'tulathromycin' ((2R,3S,4R,5R,8R,10R,11R,12S, 13S,14R)-2-ethyl-3,4,10,13-tetra-hydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethy-lamino)-ß-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopent-decan-15-one expressed as tulathromycin equivalents). This revises the maximum residue limits (MRLs) for this substance in various tissues in ovine, caprine, bovine and porcine species.

Commission Regulation 2015/414[72] amends Directive 2002/46/EC of the European Parliament and of the Council as regards (6S)-5- methyltetrahydrofolic acid, glucosamine salt used in the manufacture of food supplements.

Commission Regulation 2015/704[73] amends Regulation (EC) No 1881/2006 as regards the maximum level of non-dioxin-like PCBs in wild caught spiny dogfish (*Squalus acanthias*).

Commission Regulation 2015/705[74] lays down methods of sampling and performance criteria for the methods of analysis for the official control of the levels of erucic acid in foodstuffs and repealing Commission Directive 80/891/EEC.

Commission Implementing Regulation 2015/949[75] approves the pre-export checks carried out on certain food by certain third countries as regards the presence of certain mycotoxins. This covers ochratoxin A in wheat and wheat flour from Canada and Aflatoxins in groundnuts and almonds from the USA.

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[68] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_301_R_0003&from=EN

[69] 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

[70] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.327.01.0023.01.ENG&toc=OJ:L:2015:327:TOC

[71] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.066.01.0001.01.ENG

[72] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.068.01.0026.01.ENG

[73] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_113_R_0004&from=EN

[74] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_113_R_0005&from=EN

[75] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.156.01.0002.01.ENG

Commission Implementing Regulation 2015/1012[76] amends Annex I to Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin.

Commission Implementing Regulation 2015/1078[77] amends Regulation (EU) No 37/2010 as regards the substance 'clodronic acid (in the form of disodium salt)'. This substance is no longer to be used in animal feeds.

Commission Implementing Regulation 2015/1079[78] amends Regulation (EU) No 37/2010 as regards the substance 'hexaflumuron', specifically changing the maximum residue level in fin fish to 500 g/kg.

Commission Implementing Regulation 2015/1080[79] amends Regulation (EU) No 37/2010 as regards the substance 'propyl 4-hydroxybenzoate and its sodium salt', specifically removing any maximum residue level (MRL) providing that the substance is used as a preservative only.

Commission Implementing Regulation 2015/1308[80] amends Regulation (EU) No 37/2010 as regards the substance 'aluminium salicylate, basic'; the maximum residue limits (MRL) are modified for certain meat-producing species.

Commission Recommendation 2015/1381[81] covers the monitoring of inorganic arsenic in food.

Commission Implementing Regulation 2015/1491[82] amends Regulation (EU) No 37/2010 as regards the substance 'virginiamycin'. The limits for this substance in poultry are now 10 µg/kg (muscle & liver), 30 µg/kg (skin & fat) and 60 µg/kg (kidney).

Commission Implementing Regulation 2015/1492[83] amends Regulation (EU) No 37/2010 as regards the substance 'tylvalosin'. The limits for this substance are now 50 µg/kg in porcine tissues and 200 µg/kg in poultry eggs.

Commission Regulation 2015/1903[84] amends Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in cocoa fibre, banana chips, food supplements, dried herbs and dried spices. This adds further foodstuffs to the lists for which PAHs are given limits including herbs, spices and banana chips.

Commission Regulation 2015/1940[85] amends Regulation (EC) No 1881/2006 as regards maximum levels of ergot sclerotia in certain unprocessed cereals and the provisions on monitoring and reporting. A limit for unprocessed cereals (with the exception of corn and rice) of 0.5 g/kg has been established.

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[76] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.162.01.0026.01.ENG

[77] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.175.01.0005.01.ENG

[78] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.175.01.0008.01.ENG

[79] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.175.01.0011.01.ENG

[80] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.200.01.0011.01.ENG

[81] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.213.01.0009.01.ENG

[82] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.231.01.0007.01.ENG

[83] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.231.01.0010.01.ENG

[84] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.282.01.0011.01.ENG

[85] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.283.01.0003.01.ENG

3.1.5 Variation for certain food legislation

Regulation 2 of the S&Q Regulations states that they do not apply to (and therefore do not establish a Government Chemist function for) samples taken under legislation listed in their Schedule 1 - subject to any further information given there. For example, regulations on materials and articles in contact with food (see section 0), and on natural mineral water, spring water and bottled drinking water (see section 3.1.7) are listed in Schedule 1, and make independent provision for a Government Chemist function. Also listed are the Poultry Meat (England) Regulations 2011 (SI 452), which does not carry forward the provision of a distinct form of words for counter-analysis by the Government Chemist given in the 1984 Regulations (SI 1145); this applies currently only in England. Similar Regulations have been enacted elsewhere in the United Kingdom repealing the 1984 Regulations: The Poultrymeat (Scotland) Regulations 2011 (SSI 318); Poultrymeat Regulations (Northern Ireland) 2011 (SR 315); The Poultrymeat (Wales) Regulations 2011 (SI 1170, W. 195). These regulations continue to disapply the Food Safety (Sampling and Qualifications) Regulations 2013 (SI 264), which set out the wider Government Chemist function applicable to most food enforcement.

The Government Chemist function is disapplied in this way from the Contaminants in Food Regulations[86] too, but only to the extent that a sample falls to be prepared and analysed in accordance with the relevant EU framework Regulation[87]. The Government Chemist still expects to receive samples under these regulations and in practice much casework has arisen on contaminants in recent years.

The Food Safety (Sampling and Qualifications) Regulations in force in Scotland, Wales and Northern Ireland are disapplied in the same way by entry of the corresponding legislation into their Schedule 1.

The Country of Origin of Certain Meats (England) Regulations 2015 (SI 518)[88] modifies certain provisions of the Food Safety Act 1990, and implements 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). Similar legislation has been enacted in Northern Ireland through The Country of Origin of Certain Meats Regulations (Northern Ireland) 2015[89] (SR 321).

The Condensed Milk and Dried Milk (England) Regulations 2015 (SI 675)[90] revoke and replace the Condensed Milk and Dried Milk (England) Regulations 2003 (S.I. 2003/1596) and revoke the Condensed Milk and Dried Milk (England) (Amendment) Regulations 2008 (S.I. 2008/85). They implement Council Directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk products intended for human consumption.

The Honey (Scotland) Regulations 2015 (SSI 208)[91] revoke the Honey (Scotland) Regulation 2003 (SSI 569) as amended by the Honey (Scotland) Amendment

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[86] These were revoked and remade in 2010 to bring about the enforcement of Regulation (EU) No 165/2010, which aligns EU limits for total aflatoxins in hazelnuts, almonds and pistachios, and Brazil nuts, with those set by Codex. The latest national regulations are SI 2010/2228, SSI 2010/329, SI 2010/2394 (W206), and SR 2010/335.

[87] Regulation (EC) No 1881/2006 *setting maximum levels for certain contaminants in foodstuffs*.

[88] http://www.legislation.gov.uk/uksi/2015/518/pdfs/uksi_20150518_en.pdf

[89] http://www.legislation.gov.uk/nisr/2015/321/pdfs/nisr_20150321_en.pdf

[90] http://www.legislation.gov.uk/uksi/2015/675/pdfs/uksi_20150675_en.pdf

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

Regulations 2005 (SSI 307) and amend the Food (Scotland) Information Regulations 2014 (SSI 312). Similar regulations have been implemented in Northern Ireland by the Honey Regulations (Northern Ireland) 2015 (SR 261)[92], in England by the Honey Regulations (England) 2015[93] (SI 1348) and in Wales by the Honey (Wales) Regulations2015[94] (SI 1507, W174).

Commission Regulation 2015/728[95] amends the definition of specified risk material set out in Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

Commission Recommendation 2015/976[96] concerns the monitoring of the presence of tropane alkaloids in food. The tropane alkaloids which should be monitored are scopolamine and atropine. The method of analysis to be used for monitoring is preferably high performance liquid chromatography — mass spectrometry/(mass spectrometry) (HPLC-MS/(MS)) or, if HPLC-MS/(MS) is not possible, gas chromatography — mass spectrometry (GC-MS). The Limit of Quantification (LOQ) for atropine (racemic mixture of hyoscyamine enantiomers) and scopolamine should be preferably below 5 µg/kg and not higher 10 µg/kg for agricultural commodities, ingredients, food supplements and herbal teas and should preferably be lower than 2 µg/kg for finished foods (e.g. breakfast cereals) and 1 µg/kg for cereal-based foods for infants and young children.

Amendments

Commission Implementing Decision 2011/884/EU on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC (OJ No. L343, 23.12.2011, p.140) ("the Commission Decision"). The Commission Decision provides for import restrictions that previously applied to Bt 63 genetically modified rice to apply, with modifications, to all unauthorised GM rice. This was updated in 2013 by Commission Implementing Decision of 13 June 2013 OJ L 162 10 14.6.2013.[97] This has led to samples being submitted to determine whether rice originating from the People's Republic of China is genetically modified or contains genetically modified constituents.

Commission Regulation 2015/53[98] amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of aluminium lakes of cochineal, carminic acid, carmines (E 120) in dietary foods for special medical purposes.

Commission Regulation 2015/538[99] amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of benzoic acid — benzoates (E 210-213) in cooked shrimps in brine.

Commission Implementing Decision 2015/545[100] authorises the placing on the market of oil from the micro-algae *Schizochytrium* sp. (ATCC PTA-9695) as a

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

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

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

[95] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.116.01.0001.01.ENG

[96] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.157.01.0097.01.ENG

[97] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1423001243907&uri=CELEX:32013D0287

[98] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.088.01.0001.01.ENG

[99] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.088.01.0004.01.ENG

novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

Commission Implementing Decision 2015/546[101] authorises an extension of use of DHA and EPA-rich oil from the micro-algae *Schizochytrium* sp. as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document C(2015) 2083).

Commission Implementing Regulation 2015/596[102] amends Regulation (EC) No 606/2009 as regards the increase in the maximum total sulphur dioxide content where the climate conditions make this necessary.

Commission Regulation 2015/649[103] amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of L-leucine as a carrier for table-top sweeteners in tablets.

Commission Implementing Decision 2015/683[104] authorises the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87460 (MON 8746Ø-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Implementing Decision 2015/684[105] authorises the placing on the market of genetically modified maize NK603 (MON-ØØ6Ø3-6) and renewing the existing maize NK603 (MON-ØØ6Ø3-6) products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Implementing Decision 2015/686[106] authorises the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87769 (MON-87769-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Implementing Decision 2015/687[107] authorises the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rape MON 88302 (MON-883Ø2-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Implementing Decision 2015/694[108] authorises the placing on the market of products containing, consisting of, or produced from genetically modified soybean BPS-CV127-9 (BPS-CV127-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Implementing Decision 2015/696[109] authorises the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON87705 (MON-877Ø5-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

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[100] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.090.01.0007.01.ENG

[101] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.090.01.0011.01.ENG

[102] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.099.01.0021.01.ENG

[103] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_107_R_0003&from=EN

[104] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.112.01.0001.01.ENG

[105] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.112.01.0006.01.ENG

[106] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.112.01.0016.01.ENG

[107] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.112.01.0022.01.ENG

[108] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.112.01.0040.01.ENG

[109] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.112.01.0060.01.ENG

Commission Implementing Decision 2015/697[110] authorises the placing on the market of genetically modified maize T25 (ACS-ZMØØ3-2) and renewing the existing maize T25 (ACS-ZMØØ3-2) products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Implementing Decision 2015/698[111] authorises the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 (DP-3Ø5423-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Implementing Decision 2015/699[112] authorises the placing on the market of products containing, consisting of, or produced from genetically modified cotton T304-40 (BCS-GHØØ4-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Implementing Decision 2015/700[113] authorises the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON87708 (MON-877Ø8-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Implementing Decision 2015/701[114] authorises the placing on the market of food containing or consisting of genetically modified oilseed rape GT73, or food and feed produced from that genetically modified organism pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Regulation 2015/1005[115] amends Regulation (EC) No 1881/2006 as regards maximum levels of lead in certain foodstuffs. The maximum level for lead in some products has been reduced.

Commission Regulation 2015/1006[116] amends Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in certain foodstuffs. The maximum level for arsenic in some products has been reduced.

Commission Implementing Regulation 2015/1102[117] amends Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances. Specifically this applies to 1-methylnaphthalene, furfuryl methyl ether, difurfuryl sulphide, difurfuryl ether and ethyl furfuryl ether.

Commission Regulation 2015/1125[118] amends Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in Katsuobushi (dried bonito) and certain smoked Baltic herring. The levels revert to the higher values applicable before 31 August 2014.

Commission Regulation 2015/1137[119] amends Regulation (EC) No 1881/2006 as regards the maximum level of Ochratoxin A in *Capsicum* spp. spices. The level is reduced to 20 µg/kg, and 15 µg/kg when in mixtures with other species (pepper, ginger, nutmeg, turmeric).

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[110] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.112.01.0066.01.ENG

[111] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.112.01.0071.01.ENG

[112] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.112.01.0077.01.ENG

[113] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.112.01.0081.01.ENG

[114] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.112.01.0086.01.ENG

[115] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.161.01.0009.01.ENG

[116] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.161.01.0014.01.ENG

[117] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.181.01.0054.01.ENG

[118] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.184.01.0007.01.ENG

[119] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_185_R_0005&from=EN

The Country of Origin of Certain Meats (Wales) Regulations 2015[120] (SI 1591, W177) make provision to enforce, in Wales, certain provisions of Commission Implementing Regulation (EU) No 1337/2013 laying down rules for the application of Regulation (EU) No 1169/2011 as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry (OJ No L 335, 14.12.13, p 19) ("the Commission Regulation"). This has been implemented in Northern Ireland by the Country of Origin of Certain Meats (Northern Ireland) Regulations 2015[121] (SR 321).

Commission Implementing Decision 2015/1213[122] authorises the extension of uses of flavonoids from *Glycyrrhiza glabra* L. as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

Commission Implementing Decision 2015/1290[123] authorises the placing on the market of refined oil from the seeds of *Buglossoides arvensis* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

Commission Implementing Decision 2015/1291[124] authorises the placing on the market of heat-treated milk products fermented with *Bacteroides xylanisolvens* (DSM 23964) as a novel food under Regulation (EC) No 258/97 of the European Parliament and of the Council.

Commission Regulation 2015/13862[125] amends Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of silicon dioxide (E 551) in extracts of rosemary (E 392).

Commission Regulation 2015/1378[126] amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of riboflavins (E 101) and carotenes (E 160a) in dried potato granules and flakes.

Commission Regulation 2015/1725[127] amends Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for Ethyl lauroyl arginate (E 243).

Commission Implementing Regulation 2015/1739[128] amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of the iron tartrate as an anti-caking agent in salt and its substitute, providing specifications for this including purity, impurity levels and assay.

Commission Implementing Regulation 2015/1760[129] amends Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of the flavouring substance p-mentha-1,8-dien-7-al.

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[120] http://www.legislation.gov.uk/wsi/2015/1519/pdfs/wsi_20151519_mi.pdf

[121] http://www.legislation.gov.uk/nisr/2015/321/pdfs/nisr_20150321_en.pdf

[122] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.196.01.0019.01.ENG

[123] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.198.01.0022.01.ENG

[124] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.198.01.0026.01.ENG

[125] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.210.01.0022.01.ENG

[126] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.213.01.0001.01.ENG

[127] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.252.01.0012.01.ENG

[128] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.253.01.0003.01.ENG

[129] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.257.01.0027.01.ENG

Commission Implementing Regulation 2015/1832[130] amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Erythritol (E 968) as a flavour enhancer in energy-reduced or with no added sugars flavoured drinks at a maximum level of 1.6 %.

Commission Directive 2015/2203[131] covers the approximation of the laws of the Member States relating to caseins and caseinates intended for human consumption and repealing Council Directive 83/417/EEC. Compositional standards for these products are given in the Directive.

Commission Implementing Decision 2015/2279[132] authorises the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603 × T25 (MON-ØØ6Ø3-6 × ACS-ZMØØ3-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Implementing Decision 2015/2281[133] authorises the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 (MON-87427-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

3.1.6 Materials and articles in contact with food

The Materials and Articles in Contact with Food Regulations ('main food contact regulations') in each of the UK home countries provide for the enforcement of an EU framework Regulation[134] for materials and articles intended to come into contact directly or indirectly with food, such as processing machinery, packaging and kitchenware. The framework Regulation aims for effective functioning of the internal market, and to protect human health and the interests of consumers.

Main food contact regulations

The regulations were revised and rationalised during 2012 to cover a wider range of materials and articles, including plastics, ceramics, regenerated cellulose film (RGF), epoxy derivatives and vinyl chloride, which had previously been covered by separate regulations. Current regulations are:

- The Materials and Articles in Contact with Food (England) Regulations 2012 (SI 2619), revoking and, in part, re-enacting SI 2010/2225, SI 2009/205, SI 2006/1179 (amended by SI 2007/2790), SI 2011/231
- The Materials and Articles in Contact with Food (Scotland) Regulations 2012 (SSI 318), revoking, SSI 2006/230, SSSI 2008/261, SSI 2009/30, SSI 2010/327, SSI 2011/100
- The Materials and Articles in Contact with Food (Wales) Regulations 2012 (SI 2705, W291), revoking SI 2006/1704 (W166, amended by SI 2011/1043), SI 2009/481 (W49), SI 2010/2288, W200, SI 2011/2233, W45

[130] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.266.01.0027.01.ENG

[131] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.314.01.0001.01.ENG&toc=OJ:L:2015:314:TOC

[132] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.322.01.0058.01.ENG&toc=OJ:L:2015:322:TOC

[133] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.322.01.0067.01.ENG&toc=OJ:L:2015:322:TOC

[134] Regulation (EC) No 1935/2004 *on materials and articles intended to come into contact with food*

- The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2012 (SR 384), revoking and, in part, re-enacting SR 2010/321, SR 2009/56, SR 2011/28 and SR 2006/217.

These come under the Food Safety Act 1990 or the Food Safety (Northern Ireland) Order 1991 where appropriate, ensuring enforcement is equivalent to that of the rest of UK food law.

They provide for the enforcement of a range of EU food contact legislation, as can be seen by taking the England regulations as an example. Regulation 4 prohibits the contravention of EU framework Regulation provisions relating to general safety and consumer protection requirements, active and intelligent materials and articles, Community authorisation, labelling, declaration of compliance, and traceability. Regulation 5 gives national effect to Regulation (EC) No 2023/2006 *on good manufacturing practice for materials and articles intended to come into contact with food*. Regulation 6 fully applies Regulation (EC) No 450/2009 *on active and intelligent materials and articles intended to come into contact with food* for the first time (local authorities and port health authorities becoming the designated enforcers). Other regulations cover related procedural and administrative matters, while Parts 3 and 4 respectively contain specific requirements for vinyl chloride and regenerated cellulose film[135].

Regulation 26 of the 2012 England regulations reproduces the Government Chemist provisions from 2010. As is now usual under food law, either party to a dispute may initiate Government Chemist analysis of the retained part of a formal sample. Regulation 28 disapplies the S&Q Regulations (cf. section 3.1.5 of this paper).

The new main food contact regulations of the other home countries are of similar form, making only minor amendments to their predecessors.

Plastic materials and articles in contact with food

Regulation (EU) No 1282/2011 amends and corrects Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and adds to the positive list of monomers, other starting substances and additives; it also tightens the migration limit for melamine and corrects or clarifies the annex entries for certain substances.

National regulations applying Regulation EU 10/2011 and Directive 2011/8/EU *relating to plastic materials and articles intended to come into contact with foodstuffs* as amended include a Government Chemist referee function, and are made separately for each of the home countries. They have now been subsumed into the general materials and articles in contact with food regulations as described in the previous paragraph.

These do not alter the form of the referee function as laid down in the principal regulations, but perhaps increase the likelihood that the Government Chemist could be required to determine Bisphenol A in babies' bottles.

Regulation (EU) No 284/2011 lays down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in, or consigned from, the People's Republic of China and Hong Kong Special Administrative Region. This measure aims to control the risk of formaldehyde from melamine, or primary aromatic amines (PAA) from polyamide, some of which are carcinogenic, being released into food. Each consignment should be accompanied by documentation including analytical results showing compliance with EU requirements, the migration limits being 15 mg/kg in food for

[135] Directive 2007/42/EC *relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs* contains migration limits and testing rules.

the sum of formaldehyde and hexamethylenetetramine, and 0.01 mg/kg in food or simulants for the sum of PAA. This Regulation also provides for prior notification of imports, the designation by MS of specific points of entry into the EU, and physical checks, including laboratory analysis on 10 % of consignments. The import declaration form asks for a description of the analytical method, and, for PAA, the detection limit.

Commission Regulation (EU) No 202/2014[136] which amends Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (which includes a Government Chemist function reference). This adds 2-phenyl-3,3-bis(4-hydroxyphenyl)phthalimidine and 1,3-bis(isocyanatomethyl) to the Union list of authorised substances as food contact material (FCM) substances Nos 872 and 988. The Regulation also introduces other concomitant changes.

Commission Regulation 2015/174[137] amends and corrects Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. The amendments cover the substances (+)-tartaric acid, phenol, 1,4-butanedio formal, 1,4:3,6-dianhydrosorbitol, kaolin, activated charcoal, 1,3,5-tris (2,2-di-methylpropanamido) benzene, polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C_8-C_{22}) alcohols, fatty acids (C_8-C_{22}), esters with pentaerythritol, 2,2,4,4-tetramethylcyclobutane-1,3-diol, (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with divinylbenzene, in nanoform, 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether], ethylene-vinyl acetate copolymer wax, (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross-linked, in nanoform, polyglycerol and (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with 1,3-butanediol dimethacrylate, in nanoform.

Amendments

Commission Regulation 2015/639[138] amends Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of silicon dioxide (E 551) in polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209).

Commission Regulation 2015/1906[139] amends Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods.

3.1.7 Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations

The principal national regulations are currently:

- 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).

[136] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:062:0013:0015:EN:PDF

[137] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.030.01.0002.01.ENG

[138] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.106.01.0016.01.ENG

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

These regulations implement:

- Directive 2009/54/EC on the exploitation and marketing of natural mineral waters (recast)[140]
- 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.

In relation to spring water and bottled drinking water, Directive 98/83/EC *on the quality of water intended for human consumption*.

Among other things, the regulations prohibit the bottling of natural mineral water containing certain substances above specified limits, and prescribe the corresponding detection methods.

Taking the England regulations as an example, regulation 17 provides in the usual way under food law for a sample - a term which in this case includes one or more bottles of any water - to be divided into three parts: one for the trade contact, one for the public analyst, and one retained for analysis by the Government Chemist if required. All the UK home countries' regulations maintain the Government Chemist function, and introduce the right of a defendant to request secondary analysis (cf. section 3.1.4 of this paper) within a form of words similar to that used in the food contact materials legislation (section 0).

Amendments

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015[141] amend 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[142] (SI 1867, W274) and in Northern Ireland with the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2015[143] (SR 365).

3.2 Agriculture Act 1970

3.2.1 General

The Government Chemist remains active in this area with an intermittent flow of animal feed casework under Part IV (Fertilisers and Feeding Stuffs) of the Act. Traders are required to give their customers a 'statutory statement' describing the fertiliser or feeding stuff, including 'such particulars as may be prescribed of the nature, substance or quality of the material' (Section 68(1)), and must label stocks accordingly. Other claims for the product must be backed up with an

[140] Which repeals and replaces Directive 80/777/EEC.

[141] http://www.legislation.gov.uk/ssi/2015/363/pdfs/ssi_20150363_en.pdf

[142] http://www.legislation.gov.uk/wsi/2015/1867/pdfs/wsi_20151867_mi.pdf

[143] http://www.legislation.gov.uk/nisr/2015/365/pdfs/nisr_20150365_en.pdf

appropriate level of information. Feeding stuff containing material that is deleterious to animals must not be sold.

Within Part IV of the Act, Section 67 provides for the appointment of inspectors. Section 75 entitles a purchaser of material sold as a fertiliser or feeding stuff to have a sample taken by an inspector and analysed by the local agricultural analyst, while Section 76 provides powers for an inspector to enter premises and take samples. Section 77 prescribes the division of samples into three parts. One part is generally analysed by the area agricultural analyst 'or under his direction'[144]; another is made available to the relevant trader; and the third is retained for nine months. (A fourth part is created for the manufacturer, if distinct from the trader.)

The Government Chemist is named in Sections 78 (3) and 79 of the Act. The Government Chemist must analyse the retained ('remaining') part of a sample divided in accordance with Section 77 if:

The purchaser requested sampling, and either the purchaser, the seller or any other person who may be liable requires it

The authorities initiated sampling, and the inspector or a prosecutor requires analysis by the Government Chemist

The authorities initiated sampling, and a person charged with an offence requests the prosecutor to have the sample analysed by the Government Chemist

A court so requires 'of its own motion or on the application of either party'.

Box 3: Agriculture Act 1970

78.—(1) Where a sample of any material has been taken pursuant to the request of a purchaser under section 75 of this Act, any of the following persons, that is to say, the purchaser, the person who sold the material to him and any other person against whom a cause of action may lie in respect of the sale of that material, shall be entitled to require the inspector—

(a) to send the part retained by the inspector under section 77(1)(c) of this Act (hereafter in this section referred to as "the remaining part") for analysis to the Government Chemist;

(b) to supply the person making the request with a copy of the Government Chemist's certificate of analysis of that remaining part, whether that part was sent to the Government Chemist for analysis in pursuance of the request of that person or otherwise.

(2) Where a sample of any material has been taken by an inspector in the prescribed manner and it is intended to institute proceedings against any person for an offence under this Part of this Act and to adduce on behalf of the prosecution evidence of the result of an analysis of the sample—

(a) the prosecutor, if a person other than the inspector, shall be entitled to require the inspector—

(i) to send the remaining part of the sample for analysis to the Government Chemist;

(ii) to supply the prosecutor with a copy of the Government Chemist's certificate of analysis of that remaining part, whether that part was sent to the Government Chemist for analysis in pursuance of the request of the prosecutor or otherwise;

(b) the inspector, if he is the prosecutor, shall be entitled himself so to send that remaining part.

[144] Appropriate precautions may be needed to show that a sample is analysed 'under his direction' if the work is subcontracted outside LGC.

(3) Where a prosecutor avails himself of his rights under subsection (2) of this section he shall cause to be served with the summons a copy of the agricultural analyst's certificate of analysis and a copy of the Government Chemist's certificate of analysis; and where a prosecutor does not avail himself of his rights under that subsection he shall, not less than fourteen days before the service of the summons, cause to be served on the person charged a copy of the agricultural analyst's certificate of analysis and a notice of intended prosecution, and if, within the period of fourteen days beginning with the service of the notice, that person sends the prosecutor a written request to that effect accompanied by the amount of the fee payable by the prosecutor for the purpose under subsection (8) of this section (which shall be refunded to that person by the prosecutor if the prosecution is not brought) the prosecutor shall exercise his rights under subsection (2) of this section and the proceedings shall not be instituted until he has sent that person a copy of the Government Chemist's certificate of analysis.

(4) Where proceedings are brought against any person for an offence under this Part of this Act and evidence is given or sought to be given of the result of an analysis of a sample of any material taken by an inspector in the prescribed manner but it appears that the sample has not been analysed by the Government Chemist, the court may, of its own motion or on the application of either party, order the remaining part of the sample to be sent for analysis to the Government Chemist.

(5) Where under this section a part of a sample is sent for analysis to the Government Chemist there shall be sent with it—

(a) a copy of any document which was sent with the part of the sample sent to the agricultural analyst; and

(b) if the part is sent to the Government Chemist under subsection (2) or (4) of this section, a statement of the particulars on which the proceedings or intended proceedings are based.

(6) The Government Chemist shall analyse in such manner, if any, as may be prescribed any part of a sample sent to him under this section but, where the part is accompanied by a statement such as is mentioned in subsection (5)(b) of this section, the analysis shall be made only with respect to the particulars in the statement unless the person or court requesting or ordering the analysis requires it to extend also to other matters.

These provisions do not require parties to agree on the submission of a sample to the Government Chemist. In this respect, they are aligned with the EU right to a supplementary expert opinion.[145]

3.2.2 Fertilisers

The Fertilisers Regulations 1991 (SI 2197) as amended apply throughout Great Britain and include requirements for statutory statements, including permissible limits of variation for misstatements as to nature, substance or quality. Regulation 11 applies Part IV of the Agriculture Act 1970, which includes the provisions for analysis by the Government Chemist, for enforcement purposes.

The Fertilisers (Sampling and Analysis) Regulations 1996 (SI 1342) as amended apply throughout Great Britain. They are made in exercise of powers conferred by Section 78(6) of the 1970 Act - a reference to the Act's requirement for the Government Chemist to analyse 'in such manner ... as may be prescribed' (Box 3).

However, in implementing Regulation (EC) No 2003/2003 *relating to fertilisers*, the EC Fertilisers (England and Wales) Regulations 2006 (SI 2486) and the EC Fertilisers (Scotland) Regulations 2006 (SSI 543) disapply all the above (i.e. Part IV of the 1970 Act and the 1991 and 1996 regulations) from EC fertilisers. Regulation 3 of each set of 2006 regulations scopes the term ‘EC fertiliser’ by

[145] See section 3.1.4 above.

reference to a list of types maintained in EU legislation, as well as to establishment of the manufacturer within the Community.

Regulation (EC) No 1020/2009 *amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I, III, IV and V thereto to technical progress* adds to the list of EC types (Annex I to the principal Regulation)[146], thereby narrowing the scope of the active referee function as regards magnesium fertilisers.

Regulation (EU) No 463/2013[147] *amending Regulation (EC) No 2004/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I, II and IV thereto to technical progress* amends the definitions of 'kainit' and crude potassium salts, lignosulfonic acids, and liming materials used as fertilisers.

Commission Implementing Regulation 354/2014[148] amends and corrects Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control. Examples of the changes introduced include changing the limit of Chromium (VI) permitted from zero to 'not detectable'.

Commission Regulation 589/2014[149] which lays down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012. This prescribes sampling methods, screening methods and confirmatory methods for these compounds which take account of the most recent developments in analytical measurement technology.

Amendments

Commission Implementing Regulation 2015/399[150] amends Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,4-dimethylnaphthalene, benfuracarb, carbofuran, carbosulfan, ethephon, fenamidone, fenvalerate, fenhexamid, furathiocarb, imazapyr, malathion, picoxystrobin, spirotetramat, tepraloxydim and trifloxystrobin in or on certain products.

Commission Implementing Regulation 2015/400[151] Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bone oil, carbon monoxide, cyprodinil, dodemorph, iprodione, metaldehyde, metazachlor, paraffin oil (CAS 64742-54-7), petroleum oils (CAS 92062-35-6) and propargite in or on certain products.

Commission Implementing Regulation 2015/401[152] amends Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, chromafenozide, cyazofamid,

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[146] The 2009 Regulation also clarifies the scope of methods for the control of ammonium nitrate fertilisers of high nitrogen content (Annex III); introduces 20 CEN control methods (those for chelating agents, nitrification and urease inhibitors, and cadmium are new, while others replace existing tests), and states whether they have been ring-tested (Annex IV); and relaxes accreditation requirements for official control laboratories (Annex V).

[147] OJ No L134, 18.5.2013, p.1: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:134:0001:0014:EN:PDF

[148] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2014:106:FULL&from=EN

[149] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.164.01.0018.01.ENG

[150] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.071.01.0001.01.ENG

[151] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.071.01.0056.01.ENG

[152] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.071.01.0114.01.ENG

dicamba, difenoconazole, fenpyrazamine, fluazinam, formetanate, nicotine, penconazole, pymetrozine, pyraclostrobin, tau-fluvalinate and tebuconazole in or on certain products.

Commission Regulation 2015/552[153] amends Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,3-dichloropropene, bifenox, dimethenamid-P, prohexadione, tolylfluanid and trifluralin in or on certain products. This list of products is very extensive and goes acrosss all types of foodtsuffs.

Commission Implementing Regulation 2015/595[154] concerns a coordinated multiannual control programme of the Union for 2016, 2017 and 2018 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

Commission Implementing Regulation 2015/603[155] amends Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-naphthyloxyacetic acid, acetochlor, chloropicrin, diflufenican, flurprimidol, flutolanil and spinosad in or on certain products.

Commission Regulation 2015/896[156] amends Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for *Trichoderma polysporum* strain IMI 206039, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strains IMI 206040 and T11, *Trichoderma harzianum* strains T-22 and ITEM 908, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma asperellum* (strain T34), *Trichoderma atroviride* strain I-1237, geraniol, thymol, sucrose, ferric sulphate (iron (III) sulphate), ferrous sulphate (iron (II) sulphate) and folic acid in or on certain products.

Commission Regulation 2015/1040[157] amends Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products. This is a comprehensive Regulation applying to a wide range of food types.

Commission Implementing Regulation 2015/1101[158] which Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for difenoconazole, fluopicolide, fluopyram, isopyrazam and pendimethalin in or on certain products.

Commisssion Regulation 2015/1200[159] amends Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for amidosulfuron, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin in or on certain products.

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[153] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.092.01.0020.01.ENG

[154] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.099.01.0007.01.ENG

[155] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.100.01.0010.01.ENG

[156] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.147.01.0003.01.ENG

[157] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.167.01.0010.01.ENG

[158] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.181.01.0027.01.ENG

[159] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.195.01.0001.01.ENG

Commission Implementing Regulation 2015/1608[160] amends Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for capric acid, paraffin oil (CAS 64742-46-7), paraffin oil (CAS 72623-86-0), paraffin oil (CAS 8042-47-5), paraffin oil (CAS 97862-82-3), lime sulphur and urea in or on certain products.

Commission Regulation 2015/1910[161] amends Annexes III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for guazatine in or on certain products. The limit is now 0.05 mg/kg for the sum of guazatine and guazatine acetate, which is the lowest level which can be determined analytically.

3.2.3 Animal feed

In this field, several regulations fit together somewhat intricately within each of the home countries.

Regulation (EC) No 152/2009 *laying down the methods of sampling and analysis for the official control of feed* consolidates and updates earlier legislation. The following national regulations give effect to Regulation 152/2009:

- The Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010 (SI 2280)
- The Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) Regulations 2010 (SSI 354)
- The Feed (Sampling and Analysis and Specified Undesirable Substances) (Wales) Regulations 2010 (SI 2287, W199)
- The Feed (Sampling and Analysis and Specified Undesirable Substances) Regulations (Northern Ireland) 2010 (SR 323). As usual for animal feed, the Northern Ireland regulations refer to the Chief Agricultural Analyst rather than the Government Chemist - cf. section 3.1.3 of this paper.

These regulations amend the Agriculture Act 1970 at some points; at others, they modify its application to feeding stuffs. The Government Chemist provisions in Section 78 are modified to refer to:

A ‘retained sample’ instead of a ‘remaining part’

The taking of a sample in accordance with Regulation 152/2009, rather than ‘in the prescribed manner’.

The 2010 regulations specify themselves to be relevant feed law under the Official Feed and Food Controls Regulations. If (as rarely occurs) a sample is analysed other than in the course of official controls, at the request of the purchaser in accordance with Section 75(1) of the Act - and then by the GC under Section 78(1) - the method of analysis must now be the appropriate one, if any, set out in Regulation 152/2009. The 2010 regulations also cover administrative matters, including how to send a sample, the qualifications of analysts, and the form of the certificate of analysis.

The Feed (Hygiene and Enforcement) and the Animal Feed (England) Regulations 2013 (SI 3133)[162] and the Feed (Hygiene and Enforcement) (Wales)

[160] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.249.01.0014.01.ENG

[161] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.280.01.0002.01.ENG

[162] http://www.legislation.gov.uk/uksi/2013/3133/contents/made

Regulations 2005 (SI 3368, W265) build on the Agriculture Act 1970 but are made under the powers of the European Communities Act 1972. Part 4 of each set of regulations provided for the enforcement of Part IV of the Agriculture Act 1970 in relation to animal feeding stuffs.

In 2015 the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 consolidated the following SIs: The Genetically Modified Animal Feed (England) Regulations 2004 (S.I. 2004 No 2334); The Feed (Hygiene and Enforcement) (England) Regulations 2005 (as they enforce Regulation (EC) No. 178/2002) (S.I. 2005 No 3280) as amended ; and The Animal Feed (England) Regulations 2010 (S.I. 2010 No 2503).

The Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015 consolidated the following SIs: The Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010 (S.I. 2010 No 2280); and The Feed (Hygiene and Enforcement) (England) Regulations 2005 (S.I. 2005 No 3280) as amended.

Taking the England regulations as an example, in accordance with Regulation 24(6), the Government Chemist referee function relates to a sample of any material taken by an authorised officer in the prescribed manner[163] and appearing to him to be a feed manufactured, produced, placed on the market or intended to be placed on the market or to be material used, or intended to be used, as feed.

Within Regulation 16 of the Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015 a referee function for the Government Chemist is maintained (as 'Secondary analysis by the Government Chemist' (Box 4).

Regulation 152/2009/EU has now been amended by Commission regulation 691/2013/EU[164]. This has particular relevance for the sampling of feeds where the presence of genetically-modified feeds is suspected.

Box 4: Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015

Procedure relating to samples for analysis

15. —(1) Where an authorised officer obtains a sample and decides to have it analysed for the purpose of ascertaining whether there is or has been any contravention of specified feed law, he must divide the sample into three parts of as near as may be equal size and —

(a) cause each part to be marked sealed and fastened in the prescribed manner;

(b) send one part for analysis to the agricultural analyst for the area of the enforcement authority from which the authorised officer derives his authority;

(c) send another part to the person on whose premises the material was sampled or to his agent;

(d) retain and preserve the remaining part as an officially sealed reference sample.

(2) ...

Secondary analysis by the Government Chemist

[163] Following amendment SI 2010/2280, 'prescribed manner' now means the manner prescribed by Regulation 152/2009, or otherwise in accordance with Article 11(1) of Regulation (EC) No 882/2004.

[164] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:197:0001:0012:EN:PDF

16. —(1) Where a part of a sample sent under regulation 15(1)(b) has been analysed and —

(a) proceedings are intended to be or have been commenced against a person for an offence under specified feed law; and

(b) the prosecution intends to adduce evidence of the result of that part of the sample,

paragraphs (2) to (6) shall apply.

(2) The authorised officer —

(a) may of his own volition;

(b) shall if requested by the prosecutor (if a person other than the authorised officer); or

(c) must (subject to paragraph (6)), if requested by the defendant,

send the retained part of the sample to be analysed by the Government Chemist.

(3) The Government Chemist must analyse in the prescribed manner the part of the sample sent under paragraph (2) and send to the authorised officer a certificate of the analysis which must be signed by the Government Chemist or by a person authorised by the Government Chemist to sign.

(4) An analysis required to be made under paragraph (3) may be performed by a person acting under the direction of the Government Chemist.

(5) The authorised officer must immediately on receipt supply the prosecutor (if a person other than the authorised officer) and the defendant with a copy of the Government Chemist's certificate of analysis.

(6) Where a request is made under paragraph (2)(c) the authorised officer may give notice in writing to the defendant requesting payment of a fee specified in the notice in respect of the functions mentioned in paragraph (3), and if the specified fee does not exceed either —

(a) the cost of performing those functions; or

(b) the appropriate fee for the performance of any similar function under section 78 of the Act,

the authorised officer may in the absence of agreement by the defendant to pay the fee refuse to comply with the request made under paragraph (2)(c).

(7) In this regulation — (a) "defendant" includes a prospective defendant; and (b) "the appropriate fee" means such fee as may be fixed in accordance with the provisions of section 78(10) of the Act.

The similar Feed (Hygiene and Enforcement) (Scotland) Regulations 2005 (SSI 608) did not mention the Government Chemist; instead, the function was applied by way of legislation referencing them - namely the Feeding Stuffs (Application to Zootechnical Additives etc.) (Scotland) Regulations 2005 (SI 3362, S11), Regulation 6. The provisions relating to the Government Chemist in SI 2005/3362 applied to samples whether taken thereunder or under SSI 2005/608. However, the Feed (Hygiene and Enforcement) (Scotland) Amendment Regulations 2008 (SSI 201) transferred the provisions for secondary analysis by the Government Chemist from SI 2005/3362 to SSI 2005/608. The amending regulations preserved the scope of the Government Chemist function by inserting into SSI 2005/608 a reference to digestibility enhancers, gut flora stabilisers, and substances incorporated with the intention of favourably affecting the

environment (i.e. non-medicinal zootechnical additives). Changes to the Government Chemist provisions are limited to updating cross-references as required, and some attempts to clarify the sense. The new arrangement of the legislation is more transparent.

Regulation (EC) No 767/2009 *on the placing on the market and use of feed* aims to reduce the burden of EU legislation in this area. The national regulations providing for the enforcement of Regulation 767/2009 are:

- The Animal Feed (England) Regulations 2010 (SI 2503)
- The Animal Feed (Scotland) Regulations 2010 (SSI 373)
- The Animal Feed (Wales) Regulations 2010 (SI 2652, W220)
- The Animal Feed Regulations (Northern Ireland) 2010 (SR 355).

Some of the Feeding Stuffs Regulations of the home countries, which were revoked by the Animal Feed Regulations 2010, were made with reference to Section 78 of the Act (the Government Chemist provisions). The 2010 regulations do not carry these references forward, presumably to simplify the *vires*.

Certain references to the Government Chemist have become redundant, because they are embedded in amendments regulations which have subsequently been revoked.[165]

The Animal Feed (Scotland) Regulations 2010 have been amended by the Feed (Hygiene and Enforcement) and Animal Feed (Scotland) Amendment Regulations 2013[166] (S.S.I. 340/2013), which also amends the Feed (Hygiene and Enforcement) (Scotland) Regulations 2005.

The Feed (Hygiene and Enforcement) and the Animal Feed (Amendment) Regulations (Northern Ireland) 2013[167] (S.R. 294) amend the Animal Feed Regulations (Northern Ireland) 2010.

The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015[168] (SI 255) amends The Official Feed and Food Controls (England) Regulations 2009 (SI 3255) and revokes 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.

Commission Implementing Regulation 2015/661[169] concerns the authorisation of the preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 and *Talaromyces versatilis* sp. nov. DSM 26702 as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying (holder of the authorisation Adisseo France S.A.S.).

Commission Implementing Regulation 2015/662[170] concerns the authorisation of L-carnitine and L-carnitine L-tartrate as feed additives for all animal species.

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[165] Regulation 6 of the Feeding Stuffs (Sampling and Analysis), the Feeding Stuffs (Enforcement) and the Feeding Stuffs (Establishments and Intermediaries) (Amendment) (England) Regulations 2003 (SI 1296) mentions the Government Chemist in amending SI 1999/1663, which is now revoked. Parallels apply for Scotland (SSI 2003/277) and Wales (SI 2003/1677, W180).

[166] http://www.legislation.gov.uk/ssi/2013/340/pdfs/ssi_20130340_en.pdf

[167] http://www.legislation.gov.uk/nisr/2013/294/pdfs/nisr_20130294_en.pdf

[168] http://www.legislation.gov.uk/uksi/2015/255/pdfs/uksi_20150255_en.pdf

[169] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.110.01.0001.01.ENG

[170] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.110.01.0005.01.ENG

Commission Implementing Regulation 2015/722[171] concerns the authorisation of taurine as a feed additive for *Canidae*, *Felidae*, *Mustelidae* and carnivorous fish.

Commission Implementing Regulation 2015/723[172] concerns the authorisation of biotin as a feed additive for all animal species.

Commission Implementing Regulation 2015/724[173] concerns the authorisation of retinyl acetate, retinyl palmitate and retinyl propionate as feed additives for all animal species.

Commission Implementing Regulation 2015/897[174] concerns the authorisation of thiamine hydrochloride and thiamine mononitrate as feed additives for all animal species.

EU Developments

Commission Implementing Regulation 1390/2014[175] amends the Annex to Regulation (EU) No 37/2010, as regards the substance 'eprinomectin'. This changes the maximum residue limits (MRLs) for this substance in bovine, ovine and caprine tissues.

Commission Implementing Regulation 2015/38[176] concerns the authorisation of the preparation *of Lactobacillus acidophilus* CECT 4529 as a feed additive for laying hens and amending Regulation (EC) No 1520/2007 (holder of authorisation Centro Sperimentale del Latte).

Commission Implementing Regulation 2015/46[177] concerns the authorisation of diclazuril as a feed additive for chickens for fattening, for turkeys for fattening and for guinea fowl for fattening and breeding (holder of authorisation Huvepharma NV).

Commission Implementing Regulation 2015/47[178] concerns the authorisation of a preparation of alpha-amylase produced by *Bacillus licheniformis* (DSM 21564) as a feed additive for dairy cows (holder of the authorisation DSM Nutritional products Ltd, represented by DSM Nutritional Products Sp. Z.o.o).

Commission Implementing Regulation 2015/149[179] amends the Annex to Regulation (EU) No 37/2010 as regards the substance 'methylprednisolone'. This changes the Maximum Residue Limits (MRLs) for this substance in equine and bovine tissues and products.

Commission Implementing Regulation 2015/150[180] amends the Annex to Regulation (EU) No 37/2010 as regards the substance 'gamithromycin'. This changes the Maximum Residue Limits (MRLs) for this substance in porcine and bovine tissues.

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[171] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.115.01.0018.01.ENG

[172] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.115.01.0022.01.ENG

[173] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.115.01.0025.01.ENG

[174] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.147.01.0008.01.ENG

[175] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.369.01.0065.01.ENG

[176] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.008.01.0004.01.ENG

[177] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.009.01.0005.01.ENG

[178] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.009.01.0008.01.ENG

[179] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.026.01.0007.01.ENG

[180] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.026.01.0010.01.ENG

Commission Implementing Regulation 2015/151[181] amends the Annex to Regulation (EU) No 37/2010 as regards the substance 'doxycycline'. This changes the Maximum Residue Limits (MRLs) for this substance the tissues of all food-producing species.

Commission Implementing Regulation 2015/152[182] amends the Annex to Regulation (EU) No 37/2010 as regards the substance 'tulathromycin'. This changes the Maximum Residue Limits (MRLs) for this substance in ovine, caprine, porcine and bovine tissues.

Commission Regulation 2015/186[183] amends Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for arsenic, fluorine, lead, mercury, endosulfan and Ambrosia seeds. This covers animal feed, particularly pet foods.

Commission Implementing Regulation 2015/244[184] concerns the authorisation of Quinoline Yellow as a feed additive for non-food-producing animals at a maximum content of 25 mg/kg of complete feeding stuff with a moisture content of 12 %.

Commission Implementing Regulation 2015/264[185] concerns the authorisation of neohesperidine dihydrochalcone as a feed additive for sheep, fish, dogs, calves and certain categories of pigs. It gives a maximum level of 35 mg/kg for complete feeding stuffs with a moisture content of 12 %, and lays down the method of analysis for determining this feed additives as Thin Layer Chromatography (TLC), European Pharmacopoeia 6.0, method 01/2008:1547, and in pre-mixtures and feeding stuffs as High-Performance Liquid Chromatography with Diode-Array 2015/502Detection (HPLC-DAD).

Commission Implementing Regulation 2015/446[186] amends Regulation (EU) No 37/2010 as regards the substance 'barium selenate'. The Committee for Medicinal Products for Veterinary Use ('CVMP') confirmed its initial recommendation that there is no need to establish an MRL for barium selenate for bovine and ovine species. However, the CVMP concluded that because of the fact that the depletion of the substance and its residue selenium from an injection site is extremely slow, there is a risk that consumption of an injection site would lead to an intake of selenium greater than the established safe level. Therefore, to ensure that consumers' exposure to selenium is not above the established tolerable upper intake level, the CVMP recommended that barium selenate used in veterinary medicinal products should not be administered by injection.

Commission Implementing Regulation 2015/489[187] concerns the authorisation of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R645 as a feed additive for all animal species.

Commission Implementing Regulation 2015/502[188] concerns the authorisation of the preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive for dairy cows (holder of the authorisation Micro Bio-System Ltd).

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[181] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.026.01.0013.01.ENG

[182] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.026.01.0016.01.ENG

[183] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.031.01.0011.01.ENG

[184] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.041.01.0008.01.ENG

[185] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.045.01.0010.01.ENG

[186] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.074.01.0018.01.ENG

[187] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.078.01.0005.01.ENG

[188] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.079.01.0057.01.ENG

Commission Implementing Regulation 2015/518[189] concerns the authorisation of the preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for chickens reared for laying, minor poultry species for fattening and minor poultry species reared for laying and amending Implementing Regulation (EU) No 361/2011 as regards the compatibility with coccidiostats (holder of the authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. z o.o).

Commission Regulation 2015/786[190] defines acceptability criteria for detoxification processes applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council.

Commission Implementing Regulation 2015/861[191] concerns the authorisation of potassium iodide, calcium iodate anhydrous and coated granulated calcium iodate anhydrous as feed additives for all animal species.

Commission Implementing Regulation 2015/1020[192] concerns the authorisation of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for laying hens and minor poultry species for laying (holder of the authorisation Kemin Europa NV).

Commission Implementing Regulation 2015/1028[193] amends Implementing Decision 2014/88/EU suspending temporarily imports from Bangladesh of foodstuffs containing or consisting of betel leaves ('Piper betle') as regards its period of application (notified under document C(2015) 4187).

Commission Implementing Regulation 2015/1043[194] concerns the authorisation of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IM SD135) as a feed additive for chickens for fattening, turkeys for fattening, laying hens, weaned piglets, pigs for fattening and minor poultry species for fattening and for laying, and amending Regulations (EC) No 2148/2004, (EC) No 828/2007 and (EC) No 322/2009 (holder of authorisation Huvepharma NV).

Commission Implementing Regulation 2015/1053[195] concerns the authorisation of the preparation of *Enterococcus faecium* DSM 10663/NCIMB 10415 as a feed additive for calves for rearing, piglets, chickens for fattening, turkeys for fattening, cats and dogs and amending Regulations (EC) No 1259/2004, (EC) No 255/2005, (EC) No 1200/2005 and (EC) No 1520/2007 (holder of authorisation Chevita Tierarzneimittel-GmbH).

Commission Implementing Regulation 2015/1060[196] concerns the authorisation of betaine anhydrous and betaine hydrochloride as feed additives for all animal species.

Commission Implementing Regulation 2015/1061[197] concerns the authorisation of ascorbic acid, sodium ascorbyl phosphate, sodium calcium ascorbyl phosphate, sodium ascorbate, and calcium ascorbate and ascorbyl palmitate as feed additives for all animal species.

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[189] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.082.01.0075.01.ENG

[190] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.125.01.0010.01.ENG

[191] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.137.01.0001.01.ENG

[192] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_163_R_0003&from=EN

[193] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.163.01.0053.01.ENG

[194] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.167.01.0063.01.ENG

[195] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.171.01.0008.01.ENG

[196] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.174.01.0003.01.ENG

[197] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.174.01.0008.01.ENG

Commission Implementing Regulation 2015/1103[198] concerns the authorisation of beta-carotene as a feed additive for all animal species.

Commission Implementing Regulation 2015/1104[199] amends Implementing Regulation (EU) No 237/2012 as regards a new form of alpha-galactosidase (EC 3.2.1.22) produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* (CBS 120604) (holder of authorisation Kerry Ingredients and Flavours).

Commission Implementing Regulation 2015/1105[200] concerns the authorisation of a preparation of *Bifidobacterium animalis* ssp. animalis DSM 16284*, Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and Enterococcus faecium DSM 21913 as a feed additive for chickens reared for laying and minor poultry species other than laying, the authorisation of that feed additive for use in water for drinking for chickens for fattening and amending Regulation (EU) No 544/2013 as regards the maximum content of that feed additive in complete feedingstuff and its compatibility with coccidiostats (holder of the authorisation Biomin GmbH).

Commission Implementing Regulation 2015/1114[201] concerns the authorisation of L-valine produced by *Escherichia coli* as a feed additive for all animal species and amending Regulation (EC) No 403/2009 and Implementing Regulations (EU) No 848/2014 and (EU) No 1236/2014.

Commission Implementing Regulation 2015/1152[202] concerns the authorisation of tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol as feed additives for all animal species.

Commission Implementing Regulation 2015/1399[203] concerns the denial of authorisation of the preparation of *Bacillus toyonensis* (NCIMB 14858T) (formerly *Bacillus cereus* var. *toyo*i NCIMB 40112/CNCM I-1012) as a feed additive for cattle for fattening, rabbits for fattening, chickens for fattening, piglets (weaned), pigs for fattening, sows for reproduction and calves for rearing and the revocation of the authorisations of the preparation of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012) as a feed additive for turkeys for fattening and rabbit breeding does, amending Regulations (EC) No 256/2002, (EC) No 1453/2004, (EC) No 255/2005 and (EC) No 1200/2005 and repealing Regulations (EC) No 166/2008, (EC) No 378/2009 and Implementing Regulation (EU) No 288/2013.

Commission Implementing Regulation 2015/1408[204] concerns the authorisation of DL-methionyl-DL-methionine as a feed additive for fish and crustaceans.

Commission Implementing Regulation 2015/1414[205] amends Implementing Regulation (EU) No 136/2012 concerning the authorisation of sodium bisulphate as feed additive for pets and for non-food producing animals. This gives a minimum purity for this substance (95.2 %) as well as the method of analysis (titrimetry).

Commission Implementing Regulation 2015/1415[206] concerns the authorisation of astaxanthin as a feed additive for fish, crustaceans and ornamental fish. This

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[198] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.181.01.0057.01.ENG

[199] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.181.01.0061.01.ENG

[200] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.181.01.0065.01.ENG

[201] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.182.01.0018.01.ENG

[202] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.187.01.0005.01.ENG

[203] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.217.01.0001.01.ENG

[204] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.219.01.0003.01.ENG

[205] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.220.01.0003.01.ENG

[206] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.220.01.0007.01.ENG

gives a minimum purity for the substance (96 %), a limit for other carotenoids (5 %) and a method of analysis (HPLVC with visible spectrophotometric detection).

Commission Implementing Regulation 2015/1416[207] concerns the authorisation of sodium bisulphate as feed additive for all animal species. This also gives a minimum purity for this substance (95.2 %) as well as the method of analysis (titrimetry).

Commission Implementing Regulation 2015/1417[208] concerns the authorisation of diclazuril as a feed additive for rabbits for fattening and for breeding (holder of the authorisation Huvepharma NV). This gives the concentration of diclazuril in an additive (5 g/kg) to be added to a pre-mixture, which in turn has a concentration of 12 & overall. Measurement of diclazuril is by reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280nm (Commission Regulation (EC) No 152/2009.

Commission Implementing Regulation 2015/1426[209] concerns the authorisation of the preparation of benzoic acid, thymol, eugenol and piperine as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species for fattening and reared for laying (holder of the authorisation DSM Nutritional Product).

Commission Implementing Regulation 2015/1486[210] concerns the authorisation of canthaxanthin as feed additive for certain categories of poultry, ornamental fish and ornamental birds. This gives the concentration of canthaxanthin as 96 %, maximum impurity levels of 100 mg/kg triphenylphosphine oxide and 600 mg/kg Measurement of canthaxanthin is by visible spectrophotometry or, for mixtures, normal phase high performance liquid chromatography (HPLC) using visible detection at 466nm.

Commission Implementing Regulation 2015/1489[211] concerns the authorisation of the preparation of *Lactobacillus plantarum* NCIMB 30238 and *Pediococcus pentosaceus* NCIMB 30237 as a feed additive for all animal species.

Commission Implementing Regulation 2015/1490[212] concerns the authorisation of the preparation of carvacrol, cinnamaldehyde and capsicum oleoresin as a feed additive for chickens for fattening (holder of the authorisation Pancosma France S.A.S.). This lists the specification for these substances and specifies the analytical method to be used to measure them in feed additives as GC-FID.

Commission Implementing Regulation 2015/1747[213] corrects the Annex to Regulation (EU) No 26/2011 concerning the authorisation of vitamin E as a feed additive for all animal species.

Commission Regulation 2015/2294[214] amends Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of a new functional group of feed additives.

Commission Implementing Regulation 2015/2304[215] concerns the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase

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[207] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.220.01.0011.01.ENG

[208] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.220.01.0015.01.ENG

[209] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.223.01.0006.01.ENG

[210] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.229.01.0005.01.ENG

[211] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.231.01.0001.01.ENG

[212] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.231.01.0004.01.ENG

[213] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.256.01.0007.01.ENG

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

produced by *Talaromyces versatilis* sp. nov. IMI CC 378536 and *Talaromyces versatilis* sp. nov DSM 26702 as a feed additive for turkeys for fattening and for breeding (holder of the authorisation Adisseo France S.A.S.).

Commission Implementing Regulation 2015/2305[216] concerns the authorisation of a preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma citrinoviride* Bisset (IM SD142) as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets, and amending Regulations (EC) No 2148/2004 and (EC) No 1520/2007 (holder of authorisation Huvepharma NV).

Commission Implementing Regulation 2015/2306[217] concerns the authorisation of L-cysteine hydrochloride monohydrate as a feed additive for cats and dogs.

Commission Implementing Regulation 2015/2307[218] concerns the authorisation of menadione sodium bisulphite and menadione nicotinamide bisulphite as feed additives for all animal species.

Commission Implementing Regulation 2015/2382[219] concerns the authorisation of the preparation of alpha-galactosidase (EC 3.2.1.22) produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* (CBS 120604) as a feed additive for laying hens and minor poultry species for laying (holder of the authorisation Kerry Ingredients and Flavours).

GM feed

The Genetically Modified Animal Feed Regulations 2004 across Great Britain (SI 2334, SSI 433, and SI 3221, W277) execute and enforce Regulation (EC) No 1829/2003, in accordance with which GMOs for feed use, and feed containing, consisting of, or produced from GMOs must be authorised and labelled. In each case, Regulation 6 applies the provisions of the Act relating to further analysis by the Government Chemist (Box 5).

Box 5: Genetically Modified Animal Feed (England) Regulations 2004

6. - (1) The provisions of the Act listed in paragraph (2) below shall apply for the purposes of these Regulations and Regulation 1829/2003 ... as if -

(a) any reference in those provisions to a feeding stuff were a reference to feed;

(b) any reference in those provisions to the Act or any Part of it were a reference to these Regulations and Regulation 1829/2003.

(2) The provisions referred to in paragraph (1) are -

... (c) section 78(2), (3), (4), (5), (6), (7), (8) and (10) (further analysis by the Government Chemist)

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[215] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.326.01.0039.01.ENG&toc=OJ:L:2015:326:TOC

[216] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.326.01.0043.01.ENG&toc=OJ:L:2015:326:TOC

[217] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.326.01.0046.01.ENG&toc=OJ:L:2015:326:TOC

[218] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.326.01.0049.01.ENG&toc=OJ:L:2015:326:TOC

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

EU Developments

Commission Directive 2015/412[220] 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.

Medicines Act 1968

3.2.4 Status of the Government Chemist function

The Government Chemist's statutory responsibilities under this Act are wide-ranging, although they now exclude medicated animal feeding stuffs (the area in which referee samples have most recently been received). The MHRA[221] Laboratory, co-located with the Government Chemist at Teddington, is effective in resolving complex analytical issues relating to medicinal products, but the formal referee function also remains in effect.

The Act has been extensively amended over the last 40 years, so the legislation can be complex to use, but there is legislative evidence to show that the sampling provisions linked to the Government Chemist function are being actively maintained. The latest proof of this is to be found in the Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008 (SI 548), which prohibits the sale, supply or importation of medicinal products consisting of or containing *Senecio*. Article 3 provides exemptions for enforcement officials, and reference is made here to 'a sampling officer within the meaning of paragraph 1(1) of Schedule 3 to the [1968] Act', thereby ensuring that the new legislation does not hinder the sampling procedure in the Act which can lead to exercise of the Government Chemist function.

In 2008, the MHRA announced that it would review and consolidate the Act over the next 2-3 years[222]. The process is now complete with the publication of the Human Medicines Regulations 2012. This has now superseded large parts of the 1968 Act, but the Act itself has not been repealed; many sections have, however, been revoked. The 2012 Regulations continue to name the Government Chemist in the same manner as the 1968 act.

Amendments

The Human Medicines Regulations 2012[223] (SI 1916), extent UK, appears to replace the Medicines Act 1968, and in doing so repeals large parts of the 1968 Act. The Act came into force in August 2012.The new Act consolidates many of the amendments enacted since 1968 and includes Herbal Remedies in the Act. The statutory function of the Government Chemist remains unaltered, but is now covered by Schedule 31, Paragraph 24.

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

[221] Medicines and Healthcare products Regulatory Agency.

[222] MHRA press release, *Medicines legislation to be reviewed and consolidated by regulator*. 24 July 2008, http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON020760

[223] SI 2012 1916, Human Medicines Regulations 2012, HMSO http://www.legislation.gov.uk/uksi/2012/1916/pdfs/uksi_20121916_en.pdf

The Human Medicines (Amendment) Regulations 2014 (SI 490)[224] was published in March 2014 and changes the definition of some categories of medicines (particularly controlled drugs), healthcare professionals and prescription procedures. This corrects two provisions that were not properly consolidated in the 2012 Regulations because of an error. This has been enacted in Northern Ireland by the Human Medicines (Amendment) Regulations[225] (SR 323/2014).

The Human Medicines (Amendment) (No 2) Regulations 2014 (SI 1878)[226] amends some of the provisions of the Act with respect to import and sales of medicines, but has no direct impact on the Government Chemist function. This has been enacted in Northern Ireland by the Human Medicines (Amendment) (No 2) Regulations[227] (SR 324/2014). The Human Medicines (Amendment) Regulation 2015[228] and the Human Medicines (Amendment) (No 2) Regulations 2015[229] (SR 259/2015) further amend the 2012 Regulations in Northern Ireland.

The Human Medicines (Amendment) Regulations 2015[230] (SI 1503) amend the Human Medicines Act 2012 regarding the prescription only medicine naloxone hydrochloride to be supplied by drug treatment services for the purpose of saving life in an emergency. This is enacted in Northern Ireland by the Human Medicines (Amendment) (No 3) Regulation 2015[231] (SR 354).

3.2.5 Outline of the Government Chemist function

Schedule 31 Paragraph 24(1) of the Regulations names the Government Chemist (

Box 6).

Schedule 31 ('Sampling') comes under Section 327 of the Regulations, which gives power to take samples for enforcement purposes. Section 327(1 -c) enables sampling from medicinal product licence applicants. Section 329 has effect in connection with Section 327, and provides an enforcement procedure involving the Government Chemist in cases of seized materials or articles.

Schedule 31 Paragraph 1 provides that Schedule 31 has effect where a sample of a substance or article is obtained: (a) to find out whether either the Act, or an order or regulations made under it, have been contravened; or (b) for other enforcement purposes backed by such legislation.

The sampling officer authorised by the enforcement authority divides the sample into three parts (Schedule 31 Paragraph 2). One part goes to the seller (broadly speaking), one is analysed by a laboratory recognised by the enforcement authority, and, under Schedule 31 Paragraph 10(a), and one is retained for future comparison.

Section 330 provides for the purchaser of a medicinal product to submit a sample to the public analyst. In accordance with Section 330(2), the purchaser is to apply

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[224] http://www.legislation.gov.uk/uksi/2014/490/pdfs/uksi_20140490_en.pdf

[225] http://www.legislation.gov.uk/nisr/2014/323/pdfs/nisr_20140323_en.pdf

[226] http://www.legislation.gov.uk/uksi/2014/1878/pdfs/uksi_20141878_en.pdf

[227] http://www.legislation.gov.uk/nisr/2014/324/pdfs/nisr_20140324_en.pdf

[228] http://www.legislation.gov.uk/nisr/2015/178/pdfs/nisr_20150178_en.pdf

[229] http://www.legislation.gov.uk/nisr/2015/259/pdfs/nisr_20150259_en.pdf

[230] http://www.legislation.gov.uk/uksi/2015/1503/made

[231] http://www.legislation.gov.uk/nisr/2015/354/pdfs/nisr_20150354_en.pdf

part of Schedule 31, including Paragraphs 2 and 10(a), which provide scope for exercise of the Government Chemist function.

Under Schedule 31 Paragraph 24(1), a court must send the retained portion of a sample for analysis by the Government Chemist or other appropriate examination at the request of either party to the proceedings, and may do so anyway if it thinks fit. Under Paragraph 24(2), an appeal court can do likewise, if the action described in Paragraph 24(1) has not yet been taken.

Box 6: Medicines Act 1968

SCHEDULE 31 SAMPLING

24.—(1) This paragraph applies where proceedings for an offence under these Regulations relate to a substance or article of which a sample has been taken as mentioned in paragraph 1 of this Schedule.

(2) Where this paragraph applies, the part of the sample retained in pursuance of paragraph 10(a) is to be produced as evidence.

(3) The court must, if requested by a party to the proceedings, and may, in the absence of such a request, cause that part of the sample to be sent for analysis to the Government Chemist (or, in Northern Ireland, to the Government Chemist in Northern Ireland[232]) or to be sent for other examination to a laboratory specified by the court.—

3.3 Farm and Garden Chemicals Act 1967

This short Act extends to Great Britain and gives powers to make labelling regulations relating to substances used in agriculture or gardening, as pesticides or for some other plant cultivation purposes. An overview report prepared for the Local Better Regulation Office (now the Better Regulation Delivery Office - BDRO) indicates that local authorities are most likely to enforce the Act through their trading standards services[233]. The Government Chemist is mentioned in Section 4 of the Act, which lays down conditions for the use of analytical evidence in prosecuting offences. Samples for analysis are distributed by the prosecutor as follows: one to the defendant; one to an analyst 'possessing the requisite qualifications for appointment as a public analyst'; and one retained to be produced at the hearing, i.e. the referee sample (Sections 4(1) and 4(3)). The Act refers to three samples, rather than the division of a sample into three parts, (Section 4(2) is relevant here).

The way in which the Government Chemist can be approached is described in Section 4(4) (Box 7). Under Section 4(5), an appeal court can do this if it has not yet been done.

Box 7: Farm and Garden Chemicals Act 1967

4.—

[232] Cf. section 6.3 of this paper.

[233] Hatton Consultancy Limited, *Legislation Mapping Phase 2*. March 2008, http://www.lbro.org.uk/FileUploads/20081027_Legislative_Mapping_Report.pdf: see Table 2, page 14

> ... (4) If in proceedings for an offence under this Act evidence is given of the results of an analysis of the product in relation to which the offence is alleged to have been committed, the court may, if it thinks fit, and upon the request of either party shall, cause the sample produced before the court under subsection (1) of this section to be sent to the Government Chemist, who shall make an analysis and transmit to the court a certificate of the result thereof, and the cost of the analysis shall be paid by the prosecutor or the defendant as the court may order.

The Farm and Garden Chemicals Regulations 1971 (SI 729) made under the 1967 Act also extend to Great Britain. The 1971 regulations contain labelling provisions that apply to around 300 chemically diverse substances listed in a Schedule. The Government Chemist could be required to provide evidence as to whether or not a product consisted of or contained one or more of the scheduled substances. However, the 1971 Regulations are largely superseded for the time being by the Plant Protection Products Regulations 2005 (SI 1435) for England and Wales[234], the Plant Protection Products (Scotland) Regulations 2005 (SSI 331)[235], and the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (SI 716); these extend to Great Britain)[236]. Samples have not been received under the 1967 Act in recent years.

3.3.1 Related EU developments

Commission Implementing Regulation 2015/51[237] approves the active substance chromafenozide, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and allowing Member States to extend provisional authorisations granted for that active substance.

Commission Implementing Regulation 2015/58[238] amends Implementing Regulation (EU) No 540/2011 as regards the expiry date of the approval of the active substance tepraloxydim.

Commission Regulation 2015/165[239] amends Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for lactic acid, *Lecanicillium muscarium* strain Ve6, chitosan hydrochloride and *Equisetum arvense* L. in or on certain products.

Commission Implementing Regulation 2015/532[240] amends and corrects Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance copper compounds.

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[234] Regulation 27(3) of SI 2005/1435 disapplies the 1971 Regulations from plant protection products. Regulation 2 of the 2005 Regulations defines plant protection products, which are to be labelled in accordance with regulation 19 thereof. The definition of plant protection products may be amended once the underlying EU framework legislation comes into effect nationally - see Article 2 of Regulation (EC) No 1107/2009 *concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC*.

[235] In accordance with regulation 28(3) thereof; the arrangement of relevant provisions is similar to SI 2005/1435.

[236] Regulation 7(10) of SI 2009/716 provides that dangerous substances and dangerous preparations that are required to be, and in fact are, labelled in accordance with those regulations are deemed to satisfy the requirements of the 1971 Regulations.

[237] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.009.01.0022.01.ENG

[238] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.010.01.0025.01.ENG

[239] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.028.01.0001.01.ENG

[240] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.039.01.0007.01.ENG

Commission Implementing Regulation 2015/306[241] renews the approval of the active substance *Isaria fumosorosea* strain Apopka 97 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/307[242] amends Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance triclopyr.

Commission Implementing Regulation 2015/308[243] amends Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance Z,Z,Z-7,13,16,19-docosatetraen-1-yl isobutyrate.

Commission Implementing Regulation 2015/408[244] implements Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution. This regulation provides comprehensive lists of those substances which are considered to have endocrine-disrupting properties (EDCs) or are persistent, bioaccumulative and toxic (PBTs).

Commission Implementing Regulation 2015/415[245] amends Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances ethephon and fenamiphos.

Commission Implementing Regulation 215/553[246] approves the active substance cerevisane, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/707[247] concerns the non-approval of *Rheum officinale* root extract as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

Commission Implementing Regulation 2015/762[248] approves the basic substance calcium hydroxide in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Regulation 2015/846[249] amends Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels (MRLs) for acetamiprid, ametoctradin, amisulbrom, bupirimate, clofentezine, ethephon, ethirimol, fluopicolide, imazapic, propamocarb, pyraclostrobin and tau-fluvalinate in or on certain products. This is a comprehensive change of MRLs across a very wide range of products.

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[241] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.056.01.0001.01.ENG

[242] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.056.01.0006.01.ENG

[243] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.056.01.0009.01.ENG

[244] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.067.01.0018.01.ENG

[245] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1428481252138&uri=CELEX:32015R0415

[246] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.092.01.0086.01.ENG

[247] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_113_R_0007&from=EN

[248] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_120_R_0003&from=EN

[249] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.140.01.0001.01.ENG

Commission Regulation 2015/868[250] amends Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4,5-T, barban, binapacryl, bromophos-ethyl, camphechlor (toxaphene), chlorbufam, chloroxuron, chlozolinate, DNOC, di-allate, dinoseb, dinoterb, dioxathion, ethylene oxide, fentin acetate, fentin hydroxide, flucycloxuron, flucythrinate, formothion, mecarbam, methacrifos, monolinuron, phenothrin, propham, pyrazophos, quinalphos, resmethrin, tecnazene and vinclozolin in or on certain products. The residue definition for binapacryl, dinoseb, fentin acetate and fentin hydroxide has been changed; lower MRLs for some of these substances reflect the ability of laboratories to detect lower levels.

Commission Implementing Regulation 2015/1106[251] amends Implementing Regulations (EU) No 540/2011 and (EU) No 1037/2012 as regards the conditions of approval of the active substance isopyrazam.

Commission Implementing Regulation 2015/1107[252] approves the basic substance *Salix* spp. cortex, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/1108[253] approves the basic substance vinegar in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/1115[254] renews the approval of the active substance pyridate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/1116[255] approves the basic substance lecithins, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/1154[256] renews the approval of the active substance sulfosulfuron in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/1165[257] approves the active substance halauxifen-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant

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[250] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.145.01.0001.01.ENG

[251] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.181.01.0070.01.ENG

[252] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.181.01.0072.01.ENG

[253] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.181.01.0075.01.ENG

[254] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.182.01.0022.01.ENG

[255] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.182.01.0026.01.ENG

[256] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.187.01.0018.01.ENG

[257] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.188.01.0030.01.ENG

protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. This substance should have a purity greater than or equal to 93.0 %.

Commission Implementing Regulation 2015/1166[258] renews the approval of the active substance ferric phosphate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. This substance should have a purity of 703 g/kg (70.3 %), equivalent to 260 g/kg iron and 144 g/kg phosphorus.

Commission Implementing Regulation 2015/1201[259] renews the approval of the active substance fenhexamid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. Fenhexamid (N-(2,3-dichloro-4-hydroxyphenyl)-1-methylcyclohexane-1-carboxamide)mhust have a purity ≥ 97.5 %, and the following relevant impurities must not exceed the following maximum levels in the technical material:

- Toluene: 0.1 %
- 4-amino-2,3-dichlorophenol: 0.3 %

Commission Implementing Regulation 2015/1295[260] approves the active substance sulfoxaflor, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/1392[261] approves the basic substance fructose in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/1396[262] corrects Implementing Regulation (EU) No 540/2011 as regards the active substance *Bacillus subtilis* (Cohn 1872) strain QST 713, identical with strain AQ 713.

Commission Implementing Regulation 2015/1397[263] renews the approval of the active substance florasulam in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Regulation 2015/1475[264] amends Regulation (EU) No 284/2013 as regards the transitional measures applying to procedures concerning plant protection products.

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[258] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.188.01.0034.01.ENG

[259] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.195.01.0037.01.ENG

[260] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.199.01.0008.01.ENG

[261] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.215.01.0034.01.ENG

[262] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.216.01.0001.01.ENG

[263] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.216.01.0003.01.ENG

[264] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.225.01.0010.01.ENG

Commission Implementing Regulation 2015/1885[265] amends Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-D, acibenzolar-s-methyl, amitrole, bentazone, cyhalofop butyl, diquat, esfenvalerate, famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), glyphosate, iprovalicarb, isoproturon, lambda-cyhalothrin, metalaxyl-M, metsulfuron methyl, picolinafen, prosulfuron, pymetrozine, pyraflufen-ethyl, thiabendazole, thifensulfuron-methyl and triasulfuron. The approval for these substances is extended to 30 June 2016.

Commission Implementing Regulation 2015/2033[266] renews the approval of the active substance 2,4-D in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/2046[267] concerns the non-approval of *Artemisia absinthium* L. as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

Commission Implementing Regulation 2015/2047[268] renews the approval of the active substance esfenvalerate, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. The substance must have a purity greater than or equal to 83% and contain no more than 1% of toluene as an impurity.

Commission Implementing Regulation 2015/2075[269] amends Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, desmedipham, dichlorprop-P, haloxyfop-P, oryzalin and phenmedipham in or on certain products. This covers the MRLs for these pesticides across a wide range of fruits, vegetables, nuts, herbs, spices and meats.

Commission Implementing Regulation 2015/2082[270] concerns the non-approval of *Arctium lappa* L. (aerial parts) as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

Commission Implementing Regulation 2015/2083[271] concerns the non-approval of *Tanacetum vulgare* L. as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

Commission Implementing Regulation 2015/2084[272] approves the active substance flupyradifurone, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant

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

[266] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.298.01.0008.01.ENG

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

[268] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.300.01.0008.01.ENG

[269] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.302.01.0015.01.ENG

[270] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.302.01.0085.01.ENG

[271] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.302.01.0087.01.ENG

[272] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.302.01.0089.01.ENG

protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/2085[273] approves the active substance mandestrobin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/2105[274] approves the active substance flumetralin (N-(2-chloro-6-fluorobenzyl)-*N*-ethyl-α,α,α-trifluoro-2,6-dinitro-p-toluidin), as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011, providing it has a purity of mot less than 98 % and the impurity Nitrosamine (calculated as nitroso-dimethylamine) shall not exceed 0.01 % in the technical material.

Commission Implementing Regulation 2015/2198[275] approves the active substance rescalure ((3S,6R)-(3S,6S)-6-isopropenyl-3-methyldec-9-en-1-yl acetate), at a purity of not less than 75 %, and with a ratio of (3S,6R)/(3S,6S) shall be in a range of 55/45 to 45/55, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation 2015/2233[276] amends Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance haloxyfop-P.

Amendments

The above EU regulations, Directive 2009/128/EC and the original Directive 1107/2009 are implemented through national legislation in the home countries as follows:

- The Plant Protection Products (Sustainable Use) Regulations 2012 (SI 1657).

[273] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.302.01.0093.01.ENG

[274] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.305.01.0031.01.ENG

[275] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.313.01.0035.01.ENG&toc=OJ:L:2015:313:TOC

[276] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.317.01.0026.01.ENG&toc=OJ:L:2015:317:TOC

4. Authorised analysis

Where the Government Chemist is named in primary legislation as an authorised analyst, there is an implication that high standards of evidence are required. The analytical results and their interpretation need to be fit to withstand scrutiny in a court of law.

4.1 Hydrocarbon Oil Duties Act 1979

This is an active area of the statutory function - about 100 samples per month are received.

The Act extends throughout the UK and consolidates legislation on excise duties applying to fuel, particularly fuel for road vehicles. The dutiable commodities are defined in sections 1-5, including hydrocarbon oil, biodiesel and bioethanol.

4.1.1 Description of authorised analyst functions

Section 24 of the Act relates to controls on duty-free and rebated oil, and refers to Schedule 5 (Sampling) - see Box 8. According to Schedule 5 Paragraph 2(2), the person taking a sample must at the time have divided it into three parts, including the part to be analysed. One part is to be analysed by the authorised analyst, one given to the person responsible for the source vehicle or premises, and one retained for future comparison. The Government Chemist is the primary authorised analyst.

Box 8: Hydrocarbon Oil Duties Act 1979

SCHEDULE 5 SAMPLING

2.—(1) The result of an analysis of a sample shall not be admissible—

in criminal proceedings under the Customs and Excise Acts 1979; or

on behalf of the Commissioners in any civil proceedings under those Acts,

unless the analysis was made by an authorised analyst ...

5. In this Schedule "authorised analyst" means—

(a) the Government Chemist or a person acting under his direction; ...

Section 20AA of the 1979 Act, which was inserted by the Finance Act 1989, also refers to Schedule 5. Subsection (1) provides a power to make regulations allowing relief from excise duty on hydrocarbon oil and certain other payments. Subsection (2)(f) permits the regulations to 'provide for the taking of samples of hydrocarbon oil in order to ascertain whether relief should be allowed or has been properly allowed'.

4.1.2 Recent developments

The Hydrocarbon Oil (Marking and Designated Markers) (Amendment) Regulations 2015 (SI 36)[277] amends The Hydrocarbon Oil (Marking) Regulations 2002 to introduce a new UK fiscal marker for the purposes of rebated fuel (((3-(sec-butyl)-4(decyloxy)phenyl)methanetriyl)tribenzene) in the proportion of not less than 2.5 kilograms per 1,000,000 litres of oil, and also increase the

[277] http://www.legislation.gov.uk/uksi/2015/36/pdfs/uksi_20150036_en.pdf

concentration of the current colouring substance (CI Solvent Red 24) to not less than 0.4 kilograms per 1,000,000 litres of oil.

5. Expert advice

This type of function does not necessarily require samples to be analysed in the laboratory. However, the Government Chemist is generally consulted because of expertise in matters of chemical or bioanalytical science. Issues may arise in relation to specific substances or articles, and could require us to provide detailed advice. Laboratory studies may be needed as a contribution to the evidence base for our input.

5.1 Poisons Act 1972

5.1.1 Government Chemist function

This Act extends to Great Britain. Schedule 1 Paragraph 3 lists the people composing the Poisons Board. One list entry reads: 'The person who is for the time being the Government Chemist or in his absence a member of his staff nominated by him'. The Board was reconvened during 2012, with a view to reviewing the 1972 Act.

Section 1 of the Act describes the Poisons Board as an advisory committee. It advises on amendments to the Poisons List, an inventory of substances treated as poisons deriving from the Pharmacy and Poisons Act 1933, and on the making of rules[278] under Section 7 of the 1972 Act. Section 10 underpins the authority of advice given by the Poisons Board, by requiring a justification before Parliament if the Poisons Board does not concur with the Secretary of State's actions.

5.1.2 Scientific requirements

The Poisons List was set out as the Schedule to the Poisons List Order 1982 (SI 217). A few specific amendments were made by the Poisons List Order 1986 (SI 9) and the Poisons List (Amendment) Order 1992 (SI 2292). The List comprises around 100 miscellaneous inorganic, organic and organometallic substances and groupings.

Responsibility for the Poisons Board lies with the Home Office. Any new requirement is likely to result from a specific incident, such as a publicised fatality arising from inappropriate retail supply. In maintaining preparedness to exercise this expert advisory function, the Government Chemist can be guided to some extent by the identity and properties of existing Poisons List entries, but should bear in mind that an incident could involve a substance which is not yet listed, such as a novel bioactive compound. Generic capability building is most appropriate, particularly as the requirement for maintaining this legislation has been questioned because the listed chemicals are now covered by EU legislation, and are more likely to be obtained directly from chemical manufacturers than through retail outlets.

5.1.3 Recent amending legislation

The Pharmacy Order 2010 (SI 231) amends Sections 9 and 11 of the Poisons Act 1972, with the effect of transferring the function of inspecting registered pharmacies from the Royal Pharmaceutical Society of Great Britain to the new General Pharmaceutical Council. According to Article 8 of the 2010 Order, the Council must establish an inspectorate. One of the functions of inspectors is to

[278] The Poisons Rules 1982 (SI 218) as amended.

secure compliance by registered pharmacists and retail pharmacy businesses with the Act and the Poisons Rules. The Council inherits the Society's power under Section 9 of the Act, on payment, to take a sample relating to substances included in Part I of the Poisons List. (Local authority inspectors have a parallel right of sampling in relation to Part II.) While there is no direct impact on the Government Chemist function, the preservation of the inspectorate and sampling powers does suggest that the Poisons Act and Poisons List still need to be enforced, and are therefore liable to generate requirements for expert advice.

The Control of Poisons and Explosives Precursors Regulations 2015 (SI 966/2015)[279] make provisions that supplement amendments made to the Poisons Act 1972 (c.66) ("the 1972 Act") by section 90 of, and Schedule 21 to, the Deregulation Act 2015 (c. 20). Regulation 2 modifies section 3A of the 1972 Act by making specific provision about the licence verification requirements with respect to the export of regulated substances (as defined in the 1972 Act) to another Member State or despatch of the same to Northern Ireland. It states that other than provided for by this regulation nothing in section 3A applies to any export of a regulated substance from the United Kingdom.

5.2 Merchant Shipping Act 1995

5.2.1 Government Chemist function

This Act extends throughout the UK. The mention of the Government Chemist now appears in Merchant Shipping Notice 1676(M)[280], which forms an integral part of the Merchant Shipping (Life-Saving Appliances For Passenger Ships of Classes III To VI(A)) Regulations 1999 (SI 2723) and the Merchant Shipping (Life-Saving Appliances For Ships Other Than Ships Of Classes III to VI(A)) Regulations 1999 (SI 2721). The text relating to the Government Chemist function is in Schedule 13 Part 3 Section 1.1 of the Notice, and concerns test requirements for fresh water to be carried as lifeboat and life raft equipment (**Box 13**).

Box 9: Merchant Shipping Notice 1676(M)

SCHEDULE 13 SURVIVAL CRAFT EQUIPMENT AND RATIONS

PART 3 – FRESH WATER

General

1.1 The water shall comply with the UK Laboratory of the Government Chemist test requirements or the equivalent standards of another State of the European Union to confirm that the water is microbiologically and chemically suitable for drinking and conforms to World Health Organisation standards.

In predecessors to the 1999 regulations, the Schedule referring to the Government Chemist was formatted as part of the legislation. Although the formatting has now changed, a preamble states that the Notice contains Schedules which are invoked by the 1999 Regulations and are therefore a statutory obligation. This endorsement is backed up by Regulation 37(1)[281] of

[279] http://www.legislation.gov.uk/uksi/2015/966/pdfs/uksi_20150966_en.pdf

[280] http://www.mcga.gov.uk/c4mca/mcga-mld-page.htm?textobjid=220A9D3228EC6C52

[281] Regulation 37 was revoked partially (for existing passenger ships 'of Class A, B, C or D of 24 metres or over in length engaged on domestic voyages') by the Merchant Shipping (Passenger Ships on Domestic Voyages) Regulations 2000 (SI 2687).

SI 1999/2721, which requires compliance, so far as is reasonably practicable, with 'a Schedule or Schedules in MSN 1676(M)' (i.e. any and all appropriate Schedules) when certain changes are made to life-saving appliances or arrangements.

5.2.2 Scientific requirements

The role of the UK Laboratory of the Government Chemist under MSN 1676(M) is to specify test requirements. When we last discussed this function with the Maritime and Coastguard Agency (MCA)[282], we were informed that it would be superseded by international standard ISO 18813:2006 (*Ships and marine technology - survival equipment for survival craft and rescue boats*), which was duly published on 29 March 2006. However, relevant UK legislation remains in force. If the Government Chemist receives any enquiries it may be appropriate to answer them in the context of the ISO standard.

5.2.3 Recent legislation providing context for this function

We might receive enquiries in connection with legislation such as the Public Health (Ships) Regulations (Northern Ireland) 2008 (SR 333), Part III (Incoming Ships). These regulations are made under the Public Health Act (Northern Ireland) 1967, and do not mention the Government Chemist. However, they allow the inspection of a ship by an authorised officer (i.e. the medical officer, or any other officer authorised by the Health and Social Services Board under Regulation 4), which can include sampling of food or water for analysis or examination.

[282] Our contact on 24 February 2006 was with MCA's Lifesaving Appliances Policy Manager.

6. Framework legislation

The following legislation relates to the establishment of the office of Government Chemist, including arrangements in particular UK home countries, or contains developments that may affect the statutory functions over a wide front.

6.1 General

6.1.1 Freedom of Information Act 2000

The Government Chemist is listed in Schedule 1, Part VI. Section 3(1) explains that Schedule 1 is the list of bodies and people termed 'public authorities' in the Act.

6.1.2 The Co-ordination of Regulatory Enforcement (Enforcement Action) (Amendment) Order 2014

This order (S.I. 573/2014)[283] amends the Co-ordination of Regulatory Enforcement (Enforcement Action) Order 2009 (S.I. S.I. 2009/665, amended by S.I. 2013/2286) and enforces the serving of Improvement Notices under Section 10 of the Food Safety Act 1990, in respect of regulation 7 of the Fish Labelling Regulations 2013, regulation 5 of the Fish Labelling (Wales) Regulations 2013, regulation 17 of the Fruit Juices and Fruit Nectars (England) Regulations 2013 and regulation 17 of the Fruit Juices and Fruit Nectars (Wales) Regulations 2013.

6.2 Scotland

6.2.1 Scotland Act 1998 (Cross-Border Public Authorities) (Specification) Order 1999

Under the Schedule to this Order (SI 1999/1319), the Government Chemist is subject to Section 88 of the Scotland Act 1998. The Act requires Westminster to consult Edinburgh about the exercise of its powers in relation to the Government Chemist if Scotland is affected and the matter is not reserved to Westminster (Section 88(2)). A report to the Westminster Parliament (such as the Government Chemist Review) must be laid before the Scottish Parliament too (Section 88(3)).

6.2.2 Interpretation and Legislative Reform (Scotland) Act 2010

The last Government Chemist Review was laid before the Scottish Parliament under section 88(3) of the Scotland Act 1998.[284] Where an enactment authorises or requires the laying of a document other than secondary legislation before the Parliament, the procedure is defined by Section 54 of the Scottish Parliament's Interpretation and Legislative Reform (Scotland) Act 2010. Section 54(2) states: 'Unless the contrary intention appears, the reference to the laying of the document, or draft document, is to be construed as a reference to the taking of such action as is specified in standing orders of the Parliament as constituting the laying of such a document, or draft of such a document, before the Parliament.'

6.2.3 Food (Scotland) Act 2015[285]

[283] http://www.legislation.gov.uk/uksi/2014/573/pdfs/uksi_20140573_en.pdf

[284] The Scottish Parliament, Minutes of Proceedings Vol 3, No 65 Session 3 (final subheading). 14 April 2010: http://www.scottish.parliament.uk/business/chamber/mop-10/mop10-04-14.htm

[285] http://www.legislation.gov.uk/asp/2015/1/pdfs/asp_20150001_en.pdf

This establishes Food Standards Scotland and describes their structure and function. This is enforced in practice and detail by the The Food (Scotland) Act 2015 (Consequential and Transitional Provisions) Order 2015[286] 100).

6.3 Northern Ireland

Practical effects of the following legislation are summarised in section 3.1.3.

6.3.1 Administrative Provisions Act (Northern Ireland) 1928

As a result of a series of partial repeals, the last being in 1971, this Act has been substantively repealed except for the provisions relating to the Government Chemist (Box 10) - which suggests that they were saved for good reason.

Box 10: Administrative Provisions Act (Northern Ireland) 1928

Provisions as to Government Chemist for Northern Ireland

2. —

(1) The Minister of Finance shall appoint an officer to be the Government Chemist for Northern Ireland, and may remove such officer.

[Subsection (2) repealed.]

(3) The Ministry of Finance may, by regulations, provide for the exercise and performance by the Chief Agricultural Analyst for Northern Ireland of any powers and duties of the Government Chemist for Northern Ireland, which may be prescribed in such regulations; and so long as such regulations are in force the said Chief Agricultural Analyst shall, for the purpose of the prescribed powers and duties, be deemed to be the Government Chemist for Northern Ireland, and the provisions of this section and of any other enactment relating to the Government Chemist for Northern Ireland shall have effect accordingly.

(4) The Ministry of Finance shall, after consultation with the Ministries of Home Affairs and Agriculture, make such regulations as are necessary for giving effect to this section, and shall give such public notice of any appointment, place or other matter prescribed by the regulations as the Ministry of Finance thinks necessary.

(5) Nothing in this section shall prejudice the making of any arrangement under section sixty-three of the Government of Ireland Act, 1920, for the exercise and performance by the Principal Government Chemist at the Government Laboratory for Great Britain, on behalf of the Government Chemist for Northern Ireland, of any powers and duties of the last-mentioned officer.

Subsection 2(5) of the 1928 Act makes reference to Section 63 of the Government of Ireland Act, 1920, which did not name the Government Chemist but generally allowed for the Great Britain and Ireland (including Northern Ireland) authorities to make arrangements for the exercise and performance of powers and duties by each other's officers - provided that the authority making the arrangements remained fully responsible. Section 2 of the Northern Ireland Act 1998 repealed the 1920 Act. However, the Government Chemist Regulations (Northern Ireland) 1928 (No. 104), made under Section 2 of the 1928 Act, clarify the appointment (Box 11).

[286] http://www.legislation.gov.uk/ssi/2015/100/pdfs/ssi_20150100_en.pdf

Box 11: Government Chemist Regulations (Northern Ireland) 1928

1. Where, under the provisions of any Act, any article of food, drug, or other substance is to be sent or may be sent by the Justices, Court of Law, Department of the Government, or otherwise, to the Government Chemist, it shall be sent to the Government Chemist at the Government Laboratory for Great Britain, situated in London.

The preamble to these regulations states that the Minister of Finance had appointed the Government Chemist at the Government Laboratory for Great Britain, situated in London, to be the Government Chemist for Northern Ireland[287]. Regulation 3 of the 1928 Regulations states that such fees as may be payable to the Government Chemist in respect of the analysis of any article are to be retained by him.

6.3.2 Interpretation Act (Northern Ireland) 1954

The preamble to this Act states that its purpose is 'to make provision with respect to the operation, interpretation and citation of Acts of the Parliament of Northern Ireland and of instruments made thereinr.' Section 2 of the 1954 Act clarifies that it applies to these Acts and to statutory instruments made under them, whether before or after the 1954 Act was passed.

Section 43 (Definitions for official purposes) states that, in an enactment, the expression 'government chemist' (not capitals) means 'the officer appointed under section two of the Administrative Provisions Act (Northern Ireland), 1928, to be the government chemist for Northern Ireland'.

6.4 Commonwealth

Over the last three years, we have begun to review the distribution of parallel functions across the Commonwealth. Having a common antecedent, these may shed light on the establishment and effective operation of the UK Government Chemist function.

For example, in India, the Food Safety and Standards Act 2006 extends to the whole nation. Section 47 contains a familiar requirement for the division of an official sample into several parts - in this case, four. While analyses are carried out on two parts, the remaining ones are kept in safe custody by a Designated Officer. One of them is available as a back-up if the sample for official analysis is lost or damaged. If the reports of analyses conducted on behalf of the official party (appointed by Central or State Government under Section 37) and a food business operator are found to be at variance, the Designated Officer sends one of the remaining parts to the referral laboratory. The referral laboratory's decision on the dispute is final.

We aim to discuss and develop best practice alongside Commonwealth counterparts when opportunities arise.

7. Conclusion

In 2015, there have been few major changes to the legislative scope of the Government Chemist statutory functions. Again, there have been a modest number of interconnected changes to feed and food law, reflecting attempts to consolidate and ease regulatory burdens at both EU level. This update also

[287] An email to Michael Walker (Consultant Science Manager, Government Chemist Programme) from an officer of the Food Standards Agency (Northern Ireland), dated 14 December 2007, stated 'I consider that [the regulations are] sufficient evidence that such an appointment did take place.'

reflects the latest changes to a number of national regulations which are routinely revoked and remade whenever new EU legislation needs to be brought into effect. In such circumstances, the form of the Government Chemist function usually changes little, but our underlying responsibilities must often expand to take on board the new scientific implications of EU law. A comprehensive list of fresh examples has been included to illustrate this continual development and growth in our statutory remit.

The relatively modest growth in new legislation reflects the slowdown in regulation from the UK Government in the period immediately before and after the General Election of May 2015.

During 2016, having no evidence to the contrary, we expect the priorities for our casework and related scientific activity to remain food, feed and medicines.

The present update is the second funded by the Government Chemist programme 2014-17. Experience has shown that an annual update of this nature is still one of the most efficient means of retaining preparedness for the diverse demands made of the Government Chemist's expertise in measurement science.