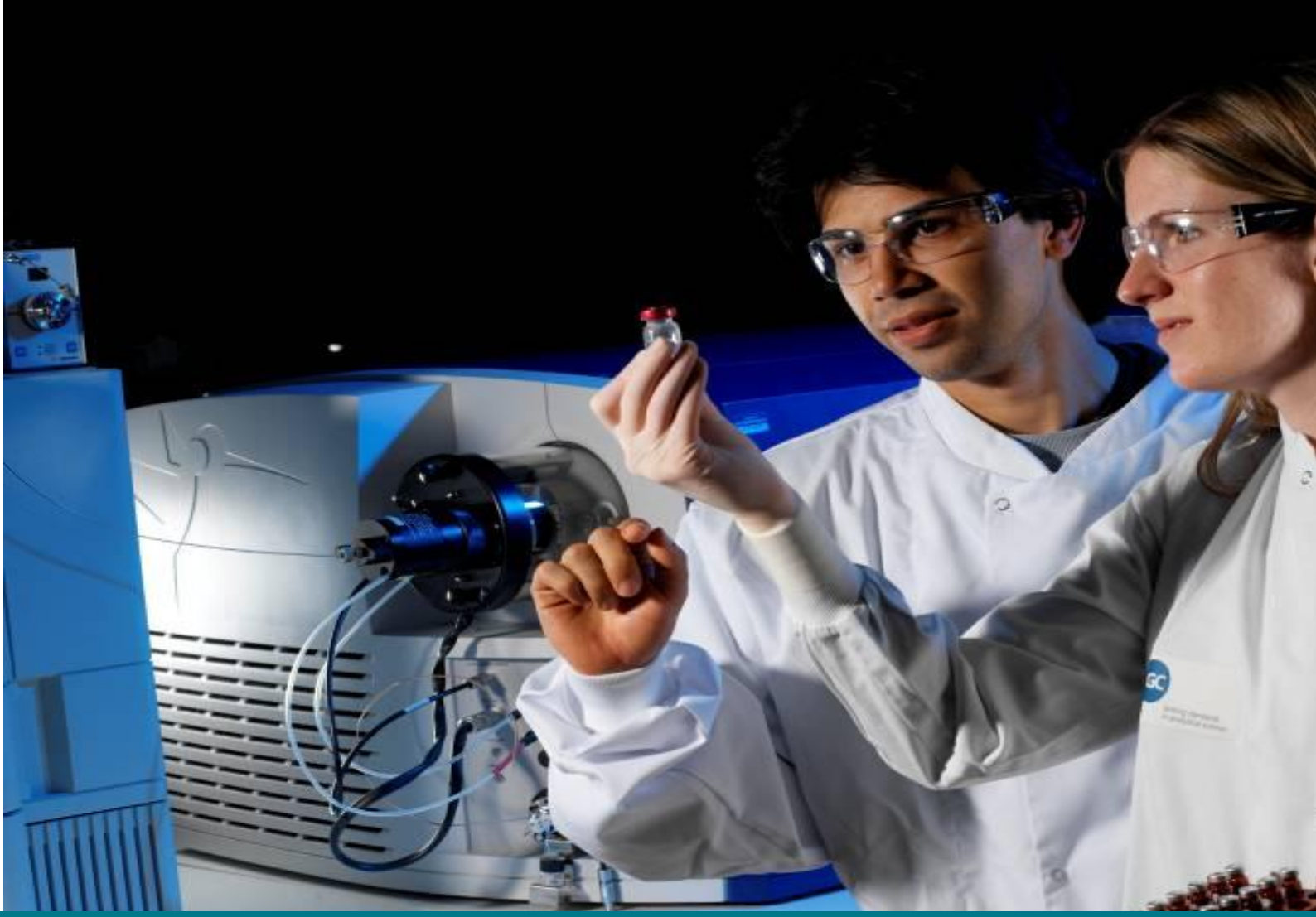

Government Chemist 2011-2014 Programme

Annual Statement of Statutory Scope

January 2014

LGC/R/2014/328

Government Chemist legislation

Annual statement of statutory scope

January 2014

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Contents

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 2013.

Table 1: Main changes to this paper since the January 2013 version

Legislation	Section	Change
Food	3.1.2	New Food Safety (Sampling and Qualifications) (England) Regulations published. Also for Scotland, Wales and Northern Ireland
Agriculture	-	No change
Medicines	3.3.1	Amendment to Human Medicines Regulations published
Farm and garden chemicals	-	No change
Hydrocarbon oil duties	-	No change
Poisons	-	No change
Merchant shipping	-	No change
Framework	-	No change

Changes in 2013 relate to the publication of the new Food Safety (Sampling and Qualifications) Regulations. The relatively small number of changes compared with previous years reflects

- the completion of a period of major review of food law by 2012;
- the European Commission's and the current government's policy to reduce the regulatory burden, and
- 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 2013[1], and comprises:

[1] Nick Boley, *Government Chemist legislation: annual statement of statutory scope*. January 2013, report number LGC/RT/2013/261, http://www.governmentchemist.org.uk/dm_documents/110307GCLegislation_cNb0V.pdf

- 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 20 December 2013 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 contact materials with formaldehyde
- 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
- Non-permitted food additives such as carbon monoxide
- Generating evidence about the application of regulated processes such as irradiation.

[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.

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 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 largely 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) (Wales) Regulations 2013 (SI 479, W55)[13] and the Food Safety (Sampling and

[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/wsi/2013/479/pdfs/wsi_20130479_mi.pdf

Qualifications) (Scotland) Regulations 2013 (S.S.I. 84)[14]. These new S&Q Regulations make two references to the Government Chemist:

- 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.

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

[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).

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).

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, although an appointment is imminent.
- 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 is expected to be published during the first half of 2014.

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, whereas the revoked 1990 S&Q Regulations required agreement between the parties to any dispute to refer the retained portion of a formal sample to the Government Chemist the 2013 measures allow the sampling officer, the prosecutor or the person

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

[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 to 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.

accused to refer the retained portion of their own volition, subject only to the accused person's agreement to pay a fee. [18].

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.

Generic and specific national application of Regulation 882/2004

For each of the UK home countries[24], the Official Feed and Food Controls Regulations transpose Regulation 882/2004.[25] 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[26], as amended by the Food (Miscellaneous Amendments) (Scotland) Regulations 2013[27]

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[18] The right to a supplementary expert opinion is outlined in Walker M and Elahi S, *The facts never lie*. Environmental Health Practitioner, 6 July 2007, http://www.cieh.org/ehp/ehp3.aspx?id=5182

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

[25] 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.

[26] 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.

- 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).[28]

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

- The Food Safety and Hygiene (England) Regulations 2013[29] (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 (Northern Ireland) 2013[30], in Scotland with the Food Safety, Food Hygiene and Official Controls (Sprouting Seeds and Miscellaneous Amendments) Regulations (Scotland) 2013[31], and the Food (Miscellaneous Amendments) (Scotland) Regulations 2013[32], and in Wales with the Food (Miscellaneous Amendments) (Wales) Regulations 2013 (S.I. 3049/2013, W.308)[33].

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)[34]
- The Feed (Sampling and Analysis and Specified Undesirable Substances) (Wales) Regulations 2010 (SI 2010 No. 2287)[35]
- The Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland) Regulations 2010 (SSI 2010 No. 354)[36]
- The Feed (Sampling and Analysis and Specified Undesirable Substances) (Northern Ireland) Regulations 2010 (SR 2010 No. 323)[37]

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)[38] –

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

[28] 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*.

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

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

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

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

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

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

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

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

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

[38] 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,

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. A new version is planned for publication late in 2013 that will be covered more fully in the 2014 update of this document.

Amendments

The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 (S.I. 2013/2210)[39] which invoke changes to Regulation (EC) No 1333/2008 as introduced by Commission Regulation (EU) No 1129/2011, Commission Regulation (EU) No 1130/2011 and Commission Regulation (EU) No 231/2012.

Similar legislation has been enacted in Scotland: The Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 (S.S.I. 2013/266)[40] and Northern Ireland: The Food Additives, Flavourings, Enzymes and Extraction Solvents (Northern Ireland) Regulations 2013 (S.R. 2013/220)[41].

The Contaminants in Food (England) Regulations 2013 (S.I. 2013/2196)[42]. These regulations revoke and re-enact with changes the Contaminants in Food (England) Regulations 2010 (S.I. 2010/2228). They make provision for (a) the continuing implementation of Council Directive 76/621/EEC relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils or fats, and of Commission Directive 80/891/EEC relating to the Community method of analysis for determining the erucic acid content in oils and fats intended to be used as such for human consumption and foodstuffs containing added oils or fats and (b) the continuing execution and enforcement of Commission Regulation 1881/2006 setting maximum levels for contaminants in foodstuffs, These amendments specifically cover Fusarium toxins in maize and maize products, dioxins and PCBs in fish liver, maximum permitted levels for certain heavy metals, maximum permitted levels for ochratoxin A, maximum levels for aflatoxins and the treatment of certain foods found to contain aflatoxins in excess of those levels, maximum levels for polycyclic aromatic hydrocarbons, revised limits for nitrates in leafy vegetables, maximum permitted levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs, maximum permitted levels of ochratoxin A, non dioxin-like PCBs and melamine in foodstuffs and maximum permitted levels for aflatoxins in dried figs.

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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.

[39] http://www.legislation.gov.uk/uksi/2013/2210/contents/made

[40] http://www.legislation.gov.uk/ssi/2013/266/contents/made

[41] http://www.legislation.gov.uk/nisr/2013/220/contents/made

[42] http://www.legislation.gov.uk/uksi/2013/2196/contents/made

Similar legislation has been enacted in Scotland (S.S.I. 217/2013)[43], Northern Ireland (S.R. 229/2013)[44] and Wales (S.I. 2493/2013, W242)[45]. The Northern Ireland legislation has been amended by the Contaminants in Food (Amendment) Regulations (Northern Ireland) 2013[46].

The Fish Labelling Regulations 2013 (S.I. 1768/2013)[47] which replaces and revokes the Fish Labelling (England) Regulations 2010 (S.I. 2010/420 as amended by S.I. 2011/1043). Certificates from a food analyst or examiner are specifically mentioned in Section 7 (1 (e). Similar legislation has been enacted in Scotland (S.S.I. 256/2013)[48] which replaces and revokes the Fish Labelling (Scotland) Regulations 2012 (S.S.I. 2010/54), Northern Ireland (S.R. 219/2013)[49] which replaces and revokes the Fish Labelling (Northern Ireland) Regulations 2010 (S.R. 2010/90 as amended by S.R. 2011/1043) and Wales 2013 (S.I. 2139/2013; W209) which replaces and revokes the Fish Labelling (Wales)[50] Regulations 2010 (S.I. 2010/797; W78).

The Fruit Juices and Fruit Nectars (England) Regulations 2013 (S.I. 2775/2013)[51] which implements Council Directive 2001/112/EC as last amended by Directive 2012/12/EU (OJ No L 115, 27.4.2012), and revokes the Fruit Juices and Fruit Nectars (England) Regulations 2003, the Fruit Juices and Fruit Nectars (England) (Amendment) Regulations 2011(b) and Regulation 9 of the Food Enzymes Regulations 2009. Similar legislation has been enacted in Scotland with The Fruit Juices and Fruit Nectars (Scotland) Regulations 2013 (S.S.I. 305/2013)[52], in Wales with The Fruit Juices and Fruit Nectars (Wales) Regulations 2013 (S.I. 2750/2013, W267)[53] and in Northern Ireland with The Fruit Juices and Fruit Nectars Regulations (Northern Ireland) 2013 (S.R. 253/2013)[54].

The Environmental Noise, Site Waste Management Plans and Spreadable Fats etc. (Revocations and Amendments) Regulations 2013[55] which revokes regulation 4 of the Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) (England) Regulations 2008 (S.I. 2008/1287), which prohibits the sale by retail of margarine unless it contains specified proportions of vitamins A and D, and make consequential amendments.

Commission Implementing Regulation 1335/2013[56] which amends Implementing Regulation (EU) No 29/2012 on marketing standards for olive oil.

Commission Implementing Regulation 1348/2013[57] which amends Regulation (EEC) No 2568/91 on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis.

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[43] http://www.legislation.gov.uk/ssi/2013/217/contents/made

[44] http://www.legislation.gov.uk/nisr/2013/229/contents/made

[45] http://www.legislation.gov.uk/wsi/2013/2493/contents/made

[46]

[47] http://www.legislation.gov.uk/uksi/2013/1768/contents/made

[48] http://www.legislation.gov.uk/ssi/2013/256/contents/made

[49] http://www.legislation.gov.uk/nisr/2013/219/contents/made

[50] http://www.legislation.gov.uk/wsi/2013/2139/contents/made

[51] http://www.legislation.gov.uk/uksi/2013/2775/pdfs/uksi_20132775_en.pdf

[52] http://www.legislation.gov.uk/ssi/2013/305/pdfs/ssi_20130305_en.pdf

[53] http://www.legislation.gov.uk/wsi/2013/2750/contents/made

[54] http://www.legislation.gov.uk/nisr/2013/253/pdfs/nisr_20130253_en.pdf

[55] http://www.legislation.gov.uk/uksi/2013/2854/pdfs/uksi_20132854_en.pdf

[56] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:335:0014:0016:EN:PDF

Commission Regulation (EU) 25/2013[58] which amends Annexes II and III 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 food additive potassium diacetate.

Commission Regulation (EU) 107/2013[59] which amends Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for melamine in canned pet food. The maximum permitted level is now 2.5 mg/kg for products containing 12 % moisture.

Commission Regulation (EU) 438/2013[60] which amends and corrects Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of certain food additives. Several changes have been made to Annex II as a result of issues arising during the transition to the new classification system within this annex.

Commission Regulation (EU) 509/2013[61] which amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of several additives in certain alcoholic beverages. This mainly concerns additives, including colours, in fruit wines and made-wine, and also covers the addition of lysozyme to beverages listed in the Polish decree on wine products.

Commission Regulation (EU) 510/2013[62] which amends Annexes I, II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of iron oxides and hydroxides (E 172), hydroxypropyl methyl cellulose (E 464) and polysorbates (E 432-436) for marking of certain fruits, specifically melons, citrus fruits and pomegranates.

Commission Regulation 545/2013[63] which adds the flavouring substance 3-acetyl-2,5-dimethylthiophene to the list of permitted food additives in Part A of Annex I to Regulation (EC) No 1334/2008.

Commission Regulation 718/2013[64] which amends Regulation (EC) No 608/2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters. This amendment states that replaced by the following: ‘3. there shall be a statement that the product is not intended for people who do not need to control their blood cholesterol level.’

Commission Regulation 723/2013[65] which amends Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of extracts of rosemary (E 392) in certain low fat meat and fish products. The permitted level is dependent on the fat content of the product to which it is added.

Commission Regulation 724/2013[66] which amends Regulation (EU) 231/2012, which in turn lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008, regarding the specification for various

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[57] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:338:0031:0067:EN:PDF

[58] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:013:0001:0005:EN:PDF

[59] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:035:0001:0002:EN:PDF

[60] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:129:0028:0033:EN:PDF

[61] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:150:0013:0016:EN:PDF

[62] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:150:0017:0020:EN:PDF

[63] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:163:0015:0016:EN:PDF

[64] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:201:0049:0050:EN:PDF

[65] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:202:0008:0010:EN:PDF

[66] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:202:0011:0016:EN:PDF

polyols used as food additives. The regulation lists the levels of impurities for mannitol, sorbitol, xylitol, maltitol and erythritol.

Commission Regulation 738/2013[67] which amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of certain additives in seaweed based fish roe analogues. This covers the use of Curcumin (E 100), Riboflavins (E 101), Cochineal, Carminic acid, Carmines (E 120), Copper complexes of chlorophylls and chlorophyllins (E 141), Plain caramels (E 150a), Vegetable carbon (E 153), Carotenes (E 160a), Paprika extract, capsanthin, capsorubin (E 160c), Beta- apo-8'-carotenal (C 30) (E 160e), Beetroot Red, betanin (E 162), Anthocyanins (E 163), Titanium dioxide (E 171), Iron oxides and hydroxides (E 172), Extracts of rosemary (E 392), Phosphoric acid – phosphates – di-, tri- and polyphosphates (E 338 - 452) and Saccharin and its Na, K and Ca salts (E 954).

Commission Regulation 739/2013[68] which amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Stigmasterol-rich plant sterols as a stabiliser in ready-to-freeze alcoholic cocktails, and the Annex to Commission Regulation (EU) No 231/2012 as regards specifications for Stigmasterol-rich plant sterols food additive, and to assign E 499 as an E- number to that food additive.

Commission Regulation 816/2013[69] which amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Neutral methacrylate copolymer and Anionic methacrylate copolymer in solid food supplements and the Annex to Commission Regulation (EU) No 231/2012 as regards the specifications for Basic methacrylate copolymer (E 1205), Neutral methacrylate copolymer and Anionic methacrylate copolymer.

Commission Regulation 817/2013[70] which amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards Octenyl succinic acid modified gum Arabic.

Commission Regulation 818/2013[71] which amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Sucrose esters of fatty acids (E 473) in flavourings for water based clear flavoured drinks. The permitted maximum levels have been changed to 15 000 mg/kg in flavourings, 30 mg/l in the final food.

Commission Regulation 913/2013[72] which amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sweeteners in certain fruit or vegetable spreads. This particularly concerns the sweeteners Acesulfame K, Cyclamic acid and its K, Na and Ca salts, Saccharin and its K, Na and Ca salts, Sucralose, Neophesperidine DC and Steviol glycosides in energy-reduced fruit or vegetable spreads and dried-fruit-based sandwich spreads, energy-reduced or with no added sugar.

Commission Regulation 985/2013[73] which amends Annex I to Regulation (EC) 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances following a review being completed of the assessment of 23 substances which are currently listed as flavouring substances.

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[67] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:204:0032:0034:EN:PDF

[68] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:204:0035:0039:EN:PDF

[69] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:230:0001:0006:EN:PDF

[70] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:230:0007:0011:EN:PDF

[71] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:230:0012:0013:EN:PDF

[72] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:252:0011:0013:EN:PDF

[73] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:273:0018:0024:EN:PDF

Commission Implementing Regulation 1019/2013[74] which amends Annex I to Regulation (EC) No 2073/2005 as regards histamine in fishery products.

Commission Regulation 1061/2013[75] which amends Regulation (EC) No 1881/2006 as regards maximum levels of the contaminants dioxins, dioxin-like PCBs and non-dioxin-like PCBs in liver of terrestrial animals.

Commission Regulation 1067/2013[76] which amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of diphosphates (E 450), triphosphates (E 451) and polyphosphates (E 452) in wet salted fish.

Commission Regulation 1069/2013[77] which amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sodium phosphates (E 339) in natural casings for sausages.

Commission Implementing Decision 2013/705/EU[78] which authorises the placing on the market of rooster comb extract as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

Commission Implementing Regulation 1321/2013[79] which establishes the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings.

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 3.1.6), 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[80] too, but only to the extent that a sample falls to be prepared and analysed in accordance with the relevant EU framework

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[74] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:282:0046:0047:EN:PDF

[75] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:289:0056:0057:EN:PDF

[76] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:289:0058:0060:EN:PDF

[77] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:289:0061:0062:EN:PDF

[78] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:322:0039:0041:EN:PDF

[79] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:333:0054:0067:EN:PDF

[80] 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.

Regulation[81]. The Government Chemist still expects to receive samples under these regulations and in practice much casework has arisen on contaminants in recent years.

The equivalent Food Safety (Sampling and Qualifications) Regulations in Scotland, Wales and Northern Ireland make the same disapplications in their Schedules 1.

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 could lead samples being submitted to determine whether rice originating from the People's Republic of China is genetically modified.

This Decision has been modified by Commission Implementing Decision 2013/287/EU[82] which adds products which may contain rice to the scope of 2011/884/EU. It also adds an additional sampling protocol to reflect this.

This decision is implemented in UK law by:

- The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2012 (SI 47) as amended by The Specified Products from China (Restriction on First Placing on the Market) (England) Amendment Regulations 2013 (SI 1683)[83], which takes into account the changes implemented by Commission Implementing Decision 2013/287/EU.
- The Specified Products from China (Restriction on First Placing on the Market) (Wales) (Amendment) Regulations 2012 (SI 64, W15) as amended by The Specified Products from China (Restriction on First Placing on the Market) (Wales) Amendment Regulations 2013 (SI 1653, W154)[84], which takes into account the changes implemented by Commission Implementing Decision 2013/287/EU.
- The Specified Products from China (Restriction on First Placing on the Market) (Scotland) Amendment Regulations 2012 (SSI 3) as amended by The Specified Products from China (Restriction on First Placing on the Market) (Scotland) Amendment Regulations 2013 (SSI 221)[85], which takes into account the changes implemented by Commission Implementing Decision 2013/287/EU.
- The Specified Products from China (Restriction on First Placing on the Market) (Amendment) Regulations (Northern Ireland) 2012 (SR 3) as amended by The Specified Products from China (Restriction on First Placing on the Market) (Northern Ireland) Amendment Regulations 2013

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

[82] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:162:0010:0014:EN:PDF

[83] http://www.legislation.gov.uk/uksi/2013/1683/contents/made

[84] http://www.legislation.gov.uk/wsi/2013/1653/contents/made

[85] http://www.legislation.gov.uk/ssi/2013/221/contents/made

(SR 180)[86], which takes into account the changes implemented by Commission Implementing Decision 2013/287/EU.

Commission Implementing Decision 2013/648/EU[87] which authorises the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × 1507 × NK603 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Implementing Decision 2013/649/EU[88] which authorises the placing on the market of pollen produced from maize MON 810 (MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Commission Implementing Decision 2016/650/EU[89] which authorises the placing on the market of products containing, consisting of, or produced from genetically modified (GM) maize MON 89034 × 1507 × MON88017 × 59122 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON- 88Ø17-3), MON89034 × 1507 × 59122 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7), 1507 × MON 88017 × 59122 (DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 × 1507 (MON-89Ø34-3 × DAS- Ø15Ø7-1), MON89034 × 59122 (MON-89Ø34-3 × DAS-59122-7), 1507 × MON88017 (DAS- Ø15Ø7-1 × MON-88Ø17-3), MON 88017 × 59122 (MON-88Ø17-3 × DAS-59122-7)) 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[90] 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

[86] http://www.legislation.gov.uk/nisr/2013/180/contents/made

[87] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:302:0038:0043:EN:PDF

[88] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:302:0044:0046:EN:PDF

[89] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:302:0047:0052:EN:PDF

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

- 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
- 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[91].

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

[91] 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.

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 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.

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).

These regulations implement:

- Directive 2009/54/EC on the exploitation and marketing of natural mineral waters (recast)[92]
- 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

None.

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

3.2 Agriculture Act 1970

3.2.1 General

The Government Chemist remains active in this area with a regular 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 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'[93]; 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—

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

(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.

(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[94], and may usefully contribute to the way in which future UK legislation prescribes the Government Chemist function.

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.

[94] See section 3.1.4 above.

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).

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 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)[95], thereby narrowing the scope of the active referee function as regards magnesium fertilisers.

Regulation (EU) No 463/2013[96] *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.

Amendments

The Plant Products (Sustainable Use) Regulations 2012 (SI 1657)[97] make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972. It appears to the Secretary of State that it is expedient for references in these Regulations to Directive 2009/128/EC of the European Parliament and of the Council establishing a framework for Community action to achieve the sustainable use of pesticides[98] to be construed as including references to Annexes I to IV of that Directive as amended from time to time.

Commission Implementing Decision (EU) 38/2013[99] allows Member States to extend provisional authorisations granted for the new active substances emamectin and maltodextrin.

Commission Regulation (EU) 500/2013[100] amends Annexes II, III and IV to Regulation 396/2005 regarding the maximum residue levels for acetamiprid, *Adoxophyes orana granulovirus* strain BV-0001, azoxystrobin, clothianidin, fenpyrazamine, heptamaloxyloglucan, metrafenone, *Paecilomyces lilacinus* strain 251, propiconazole, quizalofop-P, spiromesifen, tebuconazole, thiamethoxam and *zucchini yellow mosaik virus* - weak strain in or on certain products

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[95] 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).

[96] 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

[97] SI 1657:2012: http://www.legislation.gov.uk/uksi/2012/1657/pdfs/uksi_20121657_en.pdf

[98] OJ No L309, 24.11.2009, p.71: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0071:0086:EN:PDF

[99] OJ No L18, 22.1.2013 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:018:0017:0018:EN:PDF

[100] OJ No L151 4.6.2013: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:151:0001:0032:EN:PDF

Commission Regulation (EU) 668/2013[101] amends Annexes II and III to Regulation 396/2005 regarding the maximum residue levels for 2,4-DB, dimethomorph, indoxacarb, and pyraclostrobin in or on certain products.

Commission Regulation 786/2013[102] which amends Annex III to Regulation (EC) No 853/2004 as regards the permitted limits of yessotoxins in live bivalve molluscs. The permitted maximum is now 3.75 mg/kg.

Commission Regulation 834/2013[103] which 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 acequinocyl, bixafen, diazinon, difenoconazole, etoxazole, fenhexamid, fludioxonil, isopyrazam, lambda-cyhalothrin, profenofos and prothioconazole in or on certain products.

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.

[101] OJ No L192 15.7.13 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:192:0039:0071:EN:PDF

[102] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:220:0014:0014:EN:PDF

[103] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:233:0011:0042:EN:PDF

The Feed (Hygiene and Enforcement) (England) Regulations 2013 and the Animal Feed (England) Regulations 2013 (SI 3133)[104] and the Feed (Hygiene and Enforcement) (Wales) 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 now provides for the enforcement of Part IV of the Agriculture Act 1970 in relation to animal feeding stuffs. Within Part 4, Regulations 31 (Box 4) and 32 of both the England and Wales regulations detail a referee function for the Government Chemist. 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[105] 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.

Regulation 152/2009/EU has now been amended by Commission regulation 691/2013/EU[106]. This has particular relevance for the sampling of feeds where the presence of genetically-modified feeds is suspected.

Box 4: Feed (Hygiene and Enforcement) (England) Regulations 2005 as amended by the The Feed (Hygiene and Enforcement) (England) Regulations 2013 and the Animal Feed (England) Regulations 2013

Procedure relating to samples for analysis

30. —(1) Where in accordance with regulation 24(6) 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

31. —(1) Where a part of a sample sent under regulation 30(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 —

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

[105] 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.

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

(a) may of his own volition;

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

(c) shall (subject to paragraph (5)) if requested by the defendant,

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

(3) the Government Chemist shall analyse in the prescribed manner the part of the sample sent to him under paragraph (2) and shall send to the authorised officer a certificate of the analysis which shall be —

(a) completed in the form set out in Schedule 1 to the Feed (Sampling and Analysis and Specified Undesirable Substances) (England) Regulations 2010 and in accordance with the notes to that Schedule; and

(b) signed by the Government Chemist or by a person authorised by him to sign.

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.[107]

[107] 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).

The Animal Feed (Scotland) Regulations 2010 have been amended by the Feed (Hygiene and Enforcement) and Animal Feed (Scotland) Amendment Regulations 2013[108] (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[109] (S.R. 294) amend the Animal Feed Regulations (Northern Ireland) 2010.

EU Developments

Commission Implementing Regulation 59/2013[110] which amends the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits (MRLs) in foodstuffs of animal origin, as regards the substance monensin. The MRLs are now 2 µg/kg for muscle tissue, 10 µg/kg for fat, 50 µg/kg for liver, 10 µg/kg for kidney and 2 µg/kg for milk.

Commission Regulation 68/2013[111] gives a catalogue of feed materials. This replaces the previous catalogue, Commission Regulation 575/2011. The new regulation includes new treatment processes for feed materials, as well as amendments for maximum impurity levels arising from treatments and preparations.

Commission Implementing Regulation 96/2013[112] which concerns the authorisation of a preparation of *Lactobacillus buchneri* NCIMB 30139 and of a preparation of *Lactobacillus casei* ATTC PTA 6135 as feed additives for all animal species.

Commission Implementing Regulation 103/2013[113] which amends Regulation (EC) No 786/2007 as regards the name of the holder of the authorisation of a preparation of endo-1,4-beta-mannanase EC 3.2.1.78.

Commission Implementing Regulation 105/2013[114] which amends Implementing Regulation (EU) No 371/2011 as regards the name of the holder of the authorisation of dimethylglycine sodium salt to Taminco BVBA from Taminco NV.

Commission Implementing Regulation 115/2013[115] which amends the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance diclazuril.

Commission Implementing Regulation 116/2013[116] which amends the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance eprinomectin.

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

[109]

[110] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:021:0021:0022:EN:PDF

[111] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:029:0001:0064:EN:PDF

[112] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:033:0021:0023:EN:PDF

[113] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:034:0012:0012:EN:PDF

[114] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:034:0015:0015:EN:PDF

[115] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:038:0011:0013:EN:PDF

[116] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:038:0014:0016:EN:PDF

Commission Implementing Regulation 159/2013[117] which authorises use of a preparation of sodium benzoate, propionic acid and sodium propionate as a feed additive for pigs, poultry, bovines, sheep, goats, rabbits and horses and amends Regulations (EC) No 1876/2006 and (EC) No 757/2007.

Commission Implementing Regulation 161/2013[118] which authorises use of a preparation of sodium hydroxide as a feed additive for cats, dogs and ornamental fish.

Commission Implementing Regulation 357/2013[119] which amends Regulation (EC) No 903/2009 and Implementing Regulation (EU) No 373/2011 as regards the minimum content of a preparation of Clostridium butyricum (FERM BP-2789) as a feed additive for chickens for fattening and minor avian species (excluding laying birds).

Commission Decision 2013/205/EU[120] which allows Member States to extend provisional authorisations granted for the new active substances acequinocyl, aminopyralid, ascorbic acid, flubendiamide, gamma-cyhalothrin, ipconazole, metaflumizone, orthosulfamuron, *Pseudomonas sp.* strain DSMZ 13134, pyridalil, pyroxsulam, spiromesifen, thiencarbazone and topramezone

Commission Implementing Regulation 403/2013/EU[121] which concerns the authorisation a preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* (ATCC 74444) as a feed additive for poultry for fattening and for laying and for weaned piglets and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005 and (EC) No 1876/2006.

Commission Implementing Regulation 406/2013/EU[122] which amends the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance Prednisolone. New MRLs for Prednisolone have been set.

Commission Implementing Regulation 427/2013[123] which concerns the authorisation of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R646 as a feed additive for all animal species and amending Regulations (EC) No 1750/2006, (EC) No 634/2007 and (EC) No 900/2009 as regards the maximum supplementation with selenised yeast. The limit is now set at 0.50 mg/kg Se in total, for feed with a moisture content > 12 %, with a maximum of 0.20 mg/kg organic Se within this.

Commission Implementing Regulation 445/2013[124] which concerns the authorisation of hydroxy-analogue of selenomethionine as a feed additive for all animal species.

Commission Implementing Regulation 469/2013[125] which authorises DL-methionine, DL-methionine sodium salt, hydroxy analogue of methionine, calcium salt of hydroxy analogue of methionine, isopropyl ester of hydroxy analogue of methionine, DL-methionine protected with copolymer vinylpyridine/styrene and

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[117] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:049:0047:0049:EN:PDF

[118] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:049:0052:0054:EN:PDF

[119] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:109:0022:0022:EN:PDF

[120] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:117:0020:0022:EN:PDF

[121] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:121:0026:0029:EN:PDF

[122] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:121:0042:0043:EN:PDF

[123] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:127:0020:0022:EN:PDF

[124] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:130:0021:0023:EN:PDF

[125] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:136:0001:0008:EN:PDF

DL-methionine protected with ethylcellulose as feed additives until June 2023. Methods of analysis are also given for these substances.

Commission Implementing Regulation 544/2013[126] which authorises 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 the fattening of chickens.

Commission Implementing Regulation 601/2013[127] which authorises cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate and coated granulated cobalt(II) carbonate hydroxide (2:3) monohydrate as feed additives.

Commission Implementing Regulation 636/2013[128] which authorises the zinc chelate of methionine (1:2) as a feed additive for all animal species. This should be a powder with a minimum content of 78 % DL-methionine and a zinc content between 17.5 % and 18.5 % and a chemical formula: $C_{10}H_{20}N_2O_4S_2Zn$. The authorisation lasts until July 2023.

Commission Implementing Regulation 642/2013[129] which confirms the authorisation of niacin and niacinamide as feed additives for all animal species.

Commission Implementing Regulation 643/2013[130] which confirms the authorisation of Patent Blue V as a feed additive for non-food producing animals, amending Regulation (EC) No 358/2005.

Commission Implementing Regulation 651/2013[131] which authorises clinoptilolite of sedimentary origin as a feed additive for all animal species and amending Regulation (EC) No 1810/2005.

Commission Implementing Regulation 774/2013[132] which concerns the authorisation of a preparation of *Lactobacillus kefiri* DSM 19455 as a feed additive for all animal species.

Commission Implementing Regulation 775/2013[133] which concerns the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens reared for laying and minor poultry species other than those used for laying.

Commission Implementing Regulation 787/2013[134] which concerns the authorisation of a preparation of Bacillus subtilis (ATCC PTA-6737) as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of authorisation Kemin Europa N.V.).

Commission Implementing Regulation 795/2013[135] which concerns the authorisation of choline chloride as a feed additive for all animal species.

Commission Implementing Regulation 796/2013[136] which concerns the denial of authorisation of the substance 3-acetyl-2,5-dimethylthiophene as a feed additive.

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[126] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:163:0013:0014:EN:PDF

[127] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:172:0014:0022:EN:PDF

[128] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:183:0003:0005:EN:PDF

[129] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:186:0004:0006:EN:PDF

[130] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:186:0007:0009:EN:PDF

[131] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:189:0001:0003:EN:PDF

[132] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:217:0030:0031:EN:PDF

[133] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:217:0032:0033:EN:PDF

[134] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:220:0015:0017:EN:PDF

[135] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:224:0001:0003:EN:PDF

Commission Implementing Regulation 797/2013[137] which concerns the authorisation of a preparation of *Enterococcus faecium* NCIMB 11181 as a feed additive for calves for rearing and for fattening and weaned piglets (holder of authorisation Chr. Hansen A/S) and repealing Regulation (EC) No 1333/2004.

Commission Implementing Regulation 803/2013[138] which concerns the authorisation of folic acid as a feed additive for all animal species.

Commission Implementing Regulation 1006/2013[139] which concerns the authorisation of L-cysteine as a feed additive for all animal species.

Commission Implementing Regulation 1016/2013[140] which concerns the authorisation of a preparation of a micro-organism strain DSM 11798 of the *Coriobacteriaceae* family as a feed additive for pigs.

Commission Implementing Regulation 1040/2013[141] which concerns the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MUCL 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MUCL 49754) as a feed additive for pigs for fattening and minor porcine species for fattening other than *Sus scrofa domesticus* and turkeys for fattening (holder of authorisation Aveve NV).

Commission Implementing Regulation 1055/2013[142] which concerns the authorisation of orthophosphoric acid as a feed additive for all animal species.

Commission Implementing Regulation 1060/2013[143] which concerns the authorisation of bentonite as a feed additive for all animal species.

Commission Implementing Regulation 1061/2013[144] which concerns the authorisation of a preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for calves, kids, cats and dogs and amending Regulation (EC) No 1288/2004 (holder of the authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o).

Commission Implementing Regulation 1077/2013[145] which authorises a preparation of Enterococcus faecium NBIMCC 8270, *Lactobacillus acidophilus* NBIMCC 8242*, Lactobacillus helveticus* NBIMCC 8269, *Lactobacillus delbrueckii* ssp. *Lactis* NBIMCC 8250, *Lactobacillus delbrueckii* ssp. *bulgaricus* NBIMCC 8244, and *Streptococcus thermophilus* NBIMCC 8253 as a feed additive for suckling piglets (holder of authorisation Lactina Ltd).

Commission Implementing Regulation 1078/2013[146] which authorises fumaric acid as a feed additive for all animal species.

Commission Implementing regulation 1101/2013[147] which concerns the authorisation of a preparation of *Enterococcus faecium* DSM 7134 and

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[136] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:224:0004:0005:EN:PDF

[137] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:224:0006:0008:EN:PDF

[138] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:225:0017:0019:EN:PDF

[139] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:279:0059:0060:EN:PDF

[140] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:282:0036:0038:EN:PDF

[141] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:283:0046:0049:EN:PDF

[142] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:288:0057:0059:EN:PDF

[143] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:289:0033:0037:EN:PDF

[144] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:289:0038:0041:EN:PDF

[145] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:292:0003:0006:EN:PDF

[146] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:292:0007:0009:EN:PDF

[147] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:296:0001:0003:EN:PDF

Lactobacillus rhamnosus DSM 7133 as a feed additive for calves for rearing and amending Regulation (EC) No 1288/2004 (holder of authorisation Lactosan GmbH & CoKG).

Commission Implementing Regulation 1113/2013[148] which concerns the authorisation of preparations of *Lactobacillus plantarum* NCIMB 40027, *Lactobacillus buchneri* DSM 22501, *Lactobacillus buchneri* NCIMB 40788/CNCM I-4323, *Lactobacillus buchneri* LN 40177/ATCC PTA-6138, and *Lactobacillus buchneri* LN 4637/ATCC PTA-2494 as feed additives for all animal species.

Commission Implementing Regulation 1222/2013[149] which concerns the authorisation of propionic acid, sodium propionate and ammonium propionate as feed additives for ruminants, pigs and poultry.

Commission Implementing Regulation 1275/2013[150] which amends Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for arsenic, cadmium, lead, nitrites, volatile mustard oil and harmful botanical impurities in animal feed.

Commission Implementing Regulation 1365/2013[151] which concerns the authorisation of a preparation of alpha-galactosidase produced by Saccharomyces cerevisiae (CBS 615.94) and endo-1,4-beta-glucanase produced by Aspergillus niger (CBS 120604) as a feed additive for minor poultry species for fattening and for chickens reared for laying.

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)

[148] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:298:0029:0033:EN:PDF

[149] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:320:0016:0019:EN:PDF

[150] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:328:0086:0092:EN:PDF

[151] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:343:0031:0033:EN:PDF

3.3 Medicines Act 1968

3.3.1 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[152] 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[153]. 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[154] (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.

The Human Medicines (Amendment) Regulation 2013[155] (SI 1855) was published in August 2013 and updates the Human Medicines Regulations 2012 to take account of the implementing acts referred to in Article 85c(3) (provisions as to the sale at a distance of medicinal products) of Directive 2001/83/EC.

The Human Medicines (Amendment) (No 2) Regulation 2013[156] was published in October 2013 and updates the Human Medicines Regulations 2012 to implement

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[152] Medicines and Healthcare products Regulatory Agency.

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

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

[155] SI 2013 1855, Human Medicines (Amendment) Regulations 2013, HMSO http://www.legislation.gov.uk/uksi/2013/1855/pdfs/uksi_20131855_en.pdf

[156] SI 2013 2593 Human Medicines (Amendment) (No 2) Regulations 201344, HMSO http://www.legislation.gov.uk/uksi/2013/2593/pdfs/uksi_20132593_en.pdf

Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance and Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance.

3.3.2 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 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[157]) or to be sent for other examination to a laboratory specified by the court.—

[157] Cf. section 6.3 of this paper.

3.4 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[158]. 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.—

... (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[159], the Plant Protection Products (Scotland) Regulations 2005 (SSI 331)[160], and the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (SI 716); these extend to Great Britain)[161]. Samples have not been received under the 1967 Act in recent years.

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[158] 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

[159] 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*.

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

[161] 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.

3.4.1 Related EU developments

Commission Implementing Regulation (EU) No 17/2013[162] of 14 January 2013 approving the active substance Trichoderma atroviride (strain I-1237), 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 (EU) No 22/2013[163] of 15 January 2013 approving the active substance cyflumetofen, 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 (EU) No 34/2013[164] of 16 January 2013 amending the maximum residue levels for 2-phenylphenol, ametoctradin, Aureobasidium pullulans strains DSM 14940 and DSM 14941, cyproconazole, difenoconazole, dithiocarbamates, folpet, propamocarb, spinosad, spirodiclofen, tebufenpyrad and tetraconazole in or on certain food products.

Commission Regulation (EU) No 35/2013[165] of 16 January 2013 amending the maximum residue levels for dimethomorph, indoxacarb, pyraclostrobin and trifloxystrobin in or on certain food products.

Commission Implementing Regulation No 200/2013[166] of 8 March 2013 approving the active substance ametoctradin, 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, as corrected on 4 September 2013[167]

Commission Implementing Regulation No 350/2013[168] of 17 April 2013 approving the active substance bixafen, 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 No 355/2013[169] of 18 April 2013 approving the active substance maltodextrin, 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 No 356/2013[170] of 18 April 2013 approving the active substance halo-sulfuron methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the

[162] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:009:0005:0008:EN:PDF

[163] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:011:0008:0011:EN:PDF

[164] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:025:0001:0048:EN:PDF

[165] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:025:0049:0073:EN:PDF

[166] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:067:0001:0005:EN:PDF

[167] http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2013:235:SOM:EN:HTML

[168] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:108:0009:0012:EN:PDF

[169] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:109:0014:0017:EN:PDF

[170] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:109:0018:0021:EN:PDF

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

Commission Implementing Regulation 365/2013[171] which amends Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glufosinate.

Commission Implementing Regulation No 366/2013[172] of 22 April 2013 approving the active substance *Spodoptera littoralis nucleopolyhedrovirus*, 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 No 367/2013[173] of 22 April 2013 approving the active substance *Spodoptera littoralis nucleopolyhedrovirus*, 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 No 368/2013[174] of 22 April 2013 approving the active substance *Helicoverpa armigera nucleopolyhedrovirus*, 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 No 369/2013[175] of 22 April 2013 approving the active substance potassium phosphonates, 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 No 373/2013[176] of 22 April 2013 approving the active substance *Candida oleophila* strain O, 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 No 375/2013[177] of 22 April 2013 approving the active substance piromesifen, 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 No 378/2013[178] of 22 April 2013 approving the active substance *Paecilomyces fumosoroseus* strain FE 9901, 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.

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[171] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:111:0027:0029:EN:PDF

[172] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:111:0030:0032:EN:PDF

[173] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:111:0033:0035:EN:PDF

[174] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:111:0036:0038:EN:PDF

[175] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:111:0039:0042:EN:PDF

[176] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:112:0010:0012:EN:PDF

[177] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:112:0015:0019:EN:PDF

[178] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:113:0005:0008:EN:PDF

Commission Implementing Regulation No 532/2013[179] of 10 June 2013 amending Implementing Regulation (EU) No 540/2011 and approving the active substance carbon dioxide under Regulation (EC) No 1107/2009.

Commission Implementing Regulation No 533/2013[180] of 10 June 2013 amending Implementing Regulation (EU) No 540/2011 and extending the expiry dates for the approval of the active substances 1-methyl-cyclopropene, chlorothalonil, chlorotoluron, cypermethrin, daminozide, forchlorfenuron, indoxacarb, thiophanate-methyl and tribenuron from February 2016 to October 2017.

Commission Implementing Regulation No 546/2013[181] of 14 June 2013 amending Implementing Regulation (EU) No 540/2011 and approving the active substance eugenol under Regulation (EC) No 1107/2009.

Commission Implementing Regulation No 568/2013[182] of 18 June 2013 amending Implementing Regulation (EU) No 540/2011 and approving the active substance thymol under Regulation (EC) No 1107/2009.

Commission Implementing Regulation No 570/2013[183] of 17 June 2013 amending Implementing Regulation (EU) No 540/2011 and approving the active substance geraniol under Regulation (EC) No 1107/2009.

Commission Implementing Regulation No 762/2013[184] of 7 August 2013 amending Implementing Regulation (EU) No 540/2011 and extending the approval periods of the active substances chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, MCPA, MCPB and metiram. These are extended to 31 October 2017 for MCPA and MCPB, and to 31 January 2018 for the remainder.

Commission Implementing Regulation No 767/2013[185] of 8 August 2013 which withdraws the approval of the active substance bitertanol, 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.

Commission Regulation No 772/2013[186] of 8 August 2013 which 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 diphenylamine in or on certain products. MRLs for some products have been significantly reduced, and for other products the use of diphenylamine is not longer allowed.

Commission Implementing Decision No 431/2013[187] of 12 August which allows Member States to extend provisional authorisations granted for the active substances benalaxyl-M and valifenalate.

Commission Regulation No 777/2013[188] of 12 August 2013 which amends Annexes II, III and V to Regulation (EC) No 396/2005 as regards maximum residue levels for clodinafop, clomazone, diuron, ethalfluralin, ioxynil, iprovalicarb,

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[179] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:159:0006:0008:EN:PDF

[180] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:159:0009:0010:EN:PDF

[181] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:163:0017:0020:EN:PDF

[182] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:167:0033:0036:EN:PDF

[183] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:168:0018:0022:EN:PDF

[184] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:213:0014:0015:EN:PDF

[185] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:214:0005:0006:EN:PDF

[186] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:217:0001:0027:EN:PDF

[187] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:218:0028:0029:EN:PDF

[188] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:221:0001:0048:EN:PDF

maleic hydrazide, mepanipyrim, metconazole, prosulfocarb and tepraloxydim in or on certain products.

Commission Implementing Regulation No 781/2013[189] of 14 August which amends Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance.

Commission Implementing Regulation No 790/2013[190] of 19 August which amends Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance acetic acid. The approval is for acetic acid of a purity greater than or equal to 98.0% to be used until 31 August 2019.

Commission Implementing Regulation No 798/2013[191] of 21 August 2012 which amends Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance pyrethrins. It describes the mixtures of pyrethrins, the identities of the components and the purity allowed, and extends authorisation to 31 August 2019.

Commission Implementing Regulation No 802/2013[192] of 22 August 2013 which approves the active substance fluopyram (minimum purity 96.0 %), 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 No 827/2013[193] of 29 August 2013 which approves the active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), 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 amends the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation No 828/2013[194] of 29 August 2013 which approves the active substance emamectin, 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 amends the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation No 829/2013[195] of 29 August 2013 which approves the active substance *Pseudomonas sp*. strain DSMZ 13134, 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 amends the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation No 832/2013[196] of 30 August 2013 which approves the active substance disodium phosphonate, 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 amends the Annex to Implementing Regulation (EU) No 540/2011.

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[189] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:219:0022:0025:EN:PDF

[190] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:222:0006:0008:EN:PDF

[191] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:224:0009:0011:EN:PDF

[192] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:225:0013:0016:EN:PDF

[193] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:232:0018:0022:EN:PDF

[194] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:232:0023:0028:EN:PDF

[195] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:232:0029:0032:EN:PDF

[196] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:233:0003:0006:EN:PDF

Commission Implementing Regulation No 833/2013[197] of 30 August 2013 which approves the active substance pyriofenone, 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 amends the Annex to Implementing Regulation (EU) No 540/2011.

Commission Regulation No 834/2013[198] of 30 August 2013 which 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 acequinocyl, bixafen, diazinon, difenoconazole, etoxazole, fenhexamid, fludioxonil, isopyrazam, lambda-cyhalothrin, profenofos and prothioconazole in or on certain products.

Commission Regulation No 1004/2013[199] 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 8-hydroxyquinoline, cyproconazole, cyprodinil, fluopyram, nicotine, pendimethalin, penthiopyrad and trifloxystrobin in or on certain products.

Commission Implementing Regulation No 1031/2013[200] approves the active substance penflufen, 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 No 1089/2013[201] amends Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance kieselgur (diatomaceous earth).

Commission Implementing Regulation No 1124/2013[202] amends Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance bifenox.

Commission Implementing Regulation No 1136/2013[203] which amends Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances clothianidin, dimoxystrobin, oxamyl and pethoxamid.

Commission Implementing Regulation No 1150/2013[204] which amends Implementing Regulation (EU) No 540/2011 regarding the conditions of approval of the active substance rape seed oil.

Commission Implementing Regulation No 1138/2013[205] which 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 bitertanol, chlorfenvinphos, dodine and vinclozolin in or on certain products.

Commission Implementing Regulation No 1165/2013[206] which approves the active substance orange oil, in accordance with Regulation (EC) No 1107/2009 of

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[197] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:233:0007:0010:EN:PDF

[198] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:233:0011:0042:EN:PDF

[199] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:279:0010:0056:EN:PDF

[200] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:283:0017:0021:EN:PDF

[201] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:293:0031:0033:EN:PDF

[202] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:299:0034:0035:EN:PDF

[203] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:302:0034:0035:EN:PDF

[204] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:305:0013:0015:EN:PDF

[205] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:307:0001:0044:EN:PDF

[206] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:309:0017:0021:EN:PDF

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 No 1166/2013[207] which amends Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance dichlorprop-P.

Commission Implementing Regulation No 1175/2013[208] which approves the active substance benalaxyl-M, 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 No 1176/2013[209] which approves the active substance pyroxsulam, 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 No 1177/2013[210] which approves the active substance spirotetramat, 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 No 1177/2013[211] Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance ethoprophos.

Commission Implementing Regulation No 1187/2013[212] which approves the active substance penthiopyrad, 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 No 1192/2013[213] which approves the active substance tembotrione, 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 No 1195/2013[214] which approves the active substance sodium silver thiosulfate, 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.

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[207] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:309:0022:0024:EN:PDF

[208] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:312:0018:0022:EN:PDF

[209] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:312:0023:0027:EN:PDF

[210] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:312:0028:0032:EN:PDF

[211] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:312:0033:0035:EN:PDF

[212] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:313:0042:0046:EN:PDF

[213] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:314:0006:0010:EN:PDF

[214] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:315:0027:0031:EN:PDF

Commission Implementing Regulation No 1199/2013[215] which approves the active substance chlorantraniliprole, 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 No 1317/2013[216] which 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-D, beflubutamid, cyclanilide, diniconazole, florasulam, metolachlor and S-metolachlor, and milbemectin in or on certain products.

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).

[215] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:315:0069:0073:EN:PDF

[216] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:339:0001:0043:EN:PDF

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. fSubsection (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 following new legislation may influence the Government Chemist functions in the 1979 Act:

The Excepted Vehicles (Amendment of Schedule 1 to the Hydrocarbon Oil Duties Act 1979) Order 2013 (S.I. 2799/2013)[217] changes the definition of Excepted

[217] http://www.legislation.gov.uk/uksi/2013/2799/pdfs/uksi_20132799_en.pdf

Vehicles to cover tractors and other light agricultural vehicles used for spreading material on roads to deal with frost, ice or snow.

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[218] 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

[218] 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.

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)[219], 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).

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

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)[220] of 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)[221], 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.

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.

[220] 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).

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

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.

6.2 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.[222] 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.'

6.3 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.]

[222] 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

(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).

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[223]. 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 thereunder.’ 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'.

[223] 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.’

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

Again in 2013, there have been few major changes to the legislative scope of the Government Chemist statutory functions. However, 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 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 number of fresh examples have been included to illustrate this continual development and growth in our statutory remit.

The relatively modest growth in new legislation reflects the culmination of a period of major review of food law throughout the EU and the present government's desire to reduce the regulatory burden on business in the UK.

During 2014, having no evidence to the contrary, we expect the priorities for our casework and related scientific activity to remain food, feed and fuels.

The present update is the last funded by the Government Chemist programme 2011-14. In the subsequent programme, we will continue to update this paper every year. Experience has shown that an annual update of this nature is one of the most efficient means of retaining preparedness for the diverse demands made of the Government Chemist's expertise in measurement science.