



Government Chemist legislation

Annual statement of
statutory scope

January 2011
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**Setting standards
in analytical science**

Government Chemist legislation

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January 2011

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1. Summary

The Government Chemist currently has specific statutory functions under seven Acts of the UK Parliament. This statement is an updated record of legislation which is now in force and names the Government Chemist, or relates to the way in which the statutory functions need to be exercised. For ease of reference, Table 1 lists the main changes to the statement since the last update in January 2010.

Table 1: Main changes to this paper since the January 2010 version

Legislation	Section	Change
Food	3.1.4	New Official Feed and Food Controls Regulations, and info re further EU developments on non-animal imports
	3.1.5	Text simplified, and updated re food contaminants law
	3.1.6	New Food Contact Regulations Info on EU developments re food contact plastics
	3.1.7	Amended mineral water regulations
Agriculture	3.2.3	Extensive redraft reflecting new feed law framework New rules on combining analytical and technical tolerances
Medicines	3.3.1	Update on review of the Act
	3.3.3	Info on scientific developments deleted (no news this year)
Farm and garden chemicals	3.4.1	New section on related EU developments
Hydrocarbon oil duties	4.1.2	Further regulatory developments that could require or complicate hydrocarbon oils laboratory work
Poisons	5.1.3	Fresh evidence of related activity (Pharmacy Order 2010)
Merchant shipping	5.2	None
Framework	6.2.2	Deleted entry on the Scottish Parliament (Disqualification) Order. The 2010 Order (SI 2476) does not list the Government Chemist New info on the meaning of the laying of the Government Chemist review before the Scottish Parliament
	6.4	New section on parallel functions across the Commonwealth

Changes in 2010 relate to the updating of feed law, various regulations that have been remade to incorporate new EU measures, and the status of the Government Chemist in Scotland. Some wider developments driving up the scientific breadth and complexity implied by our scope are also reviewed or referenced. There is no sign that the overall balance of activity, spread between food, feed and fuels, will change over the coming year.

2. Introduction

This paper states the legislative scope of the Government Chemist statutory function. It amends the statement prepared in January 2010¹, and comprises:

- A record of primary and secondary legislation currently in force that names the Government Chemist or his Laboratory
- Context that helps to scope or illustrate the practical implications².

2.1 Inputs

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

- The UK Daily List³ published by TSO
- The Official Journal of the European Union (OJ)⁴.

As in previous years, we also ensured that any other relevant information or correspondence was stored at a single electronic location (or, where necessary, in a single box file), so that an orderly annual review could be conducted just before the revision of this paper.

On 14 December 2010 we checked that no mentions of 'Government Chemist' or 'LGC' in UK legislation had been missed since this paper was last updated, by conducting online searches. The official resources available to us for this purpose are the Office of Public Sector Information (OPSI) Legislation website⁵ and the UK Statute Law Database⁶. Before the latter was launched in 2006, we used to rely on the former, and found it effective. However, this year the OPSI Legislation site failed to return any results for 'Government Chemist' in 2010, whereas the Statute Law Database yielded seven.⁷ We compared the Statute Law Database results with those from our daily tracking activities, and found that we had successfully detected them all. Neither database yielded any new mentions of LGC.

In seeking to understand and advise on the implications of any changes, it is important for us 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' legislation⁸. The Statute Law Database, and, drawing upon it, the OPSI website, provide access to primary legislation in revised form. However, we still have to rely on a commercially available resource to review and interpret national secondary legislation in its latest form⁹.

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

¹ John Francis, *Government Chemist legislation: annual statement of statutory scope*. January 2010, report number LGC/RT/2009/098, http://www.governmentchemist.org.uk/dm_documents/100114GCLegislation_7Z7Bu.pdf

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.opsi.gov.uk/legislation/about_legislation

⁶ <http://www.statutelaw.gov.uk/Home.aspx>

⁷ Perhaps because the both the OPSI Legislation and Statute Law Database sites are being decommissioned. The databases are being combined under the auspices of the National Archives at <http://www.legislation.gov.uk/>

⁸ http://eur-lex.europa.eu/RECH_consolidated.do

⁹ LexisNexis Butterworths.

scanning activity. 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 would welcome suggestions.

2.2 Document outline

The legislation is classified 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 advice¹⁰.

References in statute that help to frame the status, overall character and territorial extent of the office of Government Chemist are gathered under the final section of this paper.

¹⁰ 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.

3. Referee analysis

The Government Chemist is named, and assigned a function commonly called referee analysis, by the following Acts of Parliament, or regulations made under them:

- Food Safety Act 1990
- Agriculture Act 1970
- Medicines Act 1968
- Farm and Garden Chemicals Act 1967.

We are not aware of any legal definition of the referee analyst function. It may be described as expert analysis by an independent third party to help avoid or resolve a dispute arising from two earlier sets of results, which 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 exercise 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)
- 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).

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*¹¹ explains in detail how samples for 'enforcement, defence and reference' are to be taken.

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

¹¹ Revision 1:

http://ec.europa.eu/food/food/chemicalsafety/contaminants/comm_dec_2006_504guidance_en.pdf

National Measurement System are in keeping with a dispute resolution function that responds to developments across UK industry.¹²

3.1 Food Safety Act 1990

3.1.1 Context

The Government Chemist typically receives a continual stream of samples under this Act, each of which requires intensive investigation and often, underpinning research. The circumstances, products and determinands vary widely. Examples of casework include:

- Food safety - alleged contamination by illegal dyes or fungal toxins
- Consumer choice and fraud - problems around alleged misdescriptions involving species of meat, amount of fish present, alcoholic strength or presence of GMO ingredients
- Investigation of emerging and scientifically challenging issues such as botanical, functional and allergenic constituents of food products
- Generating evidence about the application of regulated processes such as irradiation.

The Government Chemist's referee function is a demand-led service with little control over the nature or timing of casework presented for investigation. Requests for analysis often require the development at short notice of an opinion on some of the most challenging issues amenable to modern analytical science. As food technology develops, and related risks are either perceived or assessed, legislators often respond by requiring measurements that challenge the technical capabilities of analytical laboratories. The Government Chemist must be in a position to address the measurement issues that may arise.

Food law in the UK is criminal law with the associated stringent burden of proof - 'beyond reasonable doubt'. Prosecutions are usually brought under a wide range of secondary legislation to which common enforcement provisions, including the referee analyst function, apply.

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 analysis¹³. 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.

¹² 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.

¹³ 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).

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

- Regulation 7 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 which makes no explicit mention of the Government Chemist. According to Regulation 7, the sample is submitted to the Government Chemist for analysis, not examination¹⁴

- Under Regulation 4, Schedule 2 Part II names the Laboratory of the Government Chemist as the first of 14 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).

¹⁴ 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).

Box 2: Food Safety (Sampling and Qualifications) Regulations 1990

7. An authorised officer who has retained part of the sample shall submit it to the Government Chemist (or such other food analyst as the Government Chemist may direct) for analysis if-

(a) he and the owner so agree (which agreement may include who is to pay the analysis fees), or

(b) a court so orders.

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

PART II

LIST OF LABORATORIES

1. The Laboratory of the Government Chemist ...

3.1.3 Northern Ireland

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

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

The Food Safety (Sampling and Qualifications) Regulations (Northern Ireland) 1991 (SR 198) refer to the Government Chemist and the Laboratory of the Government Chemist using the same form of words as the 1990 regulations for Great Britain (

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 food samples originally procured under legislation enacted by the Department of Agriculture and Rural Development (DARD)
- The UK Government Chemist is referee analyst for cases arising under other 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.'

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 Chemist¹⁵. More generally, regulation 7(a) of the current S&Q Regulations, which dates back to 1990, requires agreement between the authorised officer and the owner for the submission of a sample to the Government Chemist; however, because the underpinning EU provision is less restrictive, consent is unlikely to be withheld¹⁶.

Generic and specific national application of Regulation 882/2004

¹⁵ Where this right has been incorporated into national law, the Government Chemist function is described as secondary analysis. The effect is that a trader can decide not carry out a defence analysis, and simply request that the referee portion of the sample is sent to the Government Chemist. The FSA Contaminants Branch has advised that the Agency will not be encouraging traders and authorised officers to send the retained portion of a sample to the Government Chemist for analysis before results are available from the public analyst sample and trader's portion. Notices provided by authorised officers will indicate that traders have the option to request that the referee sample is analysed when an adverse result from the public analyst sample has been obtained. In practice, the Government Chemist has experienced an increased workload associated with the right to a supplementary expert opinion established in EU law. To encourage a balanced, scientifically informed choice between secondary and referee analysis, 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.

¹⁶ 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>

For each of the UK home countries¹⁷, the Official Feed and Food Controls Regulations transpose Regulation 882/2004.¹⁸ 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 2007/522¹⁹
- 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).²⁰

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)²¹ – 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.

3.1.5 Variation for certain food legislation

Regulation 2 of the S&Q Regulations states that they do not apply to (and therefore do not establish a Government Chemist function for) samples taken under legislation listed in their Schedule 1 - subject to any further information given there. For example, regulations on materials and articles in contact with food (see section 0), and on natural mineral water, spring water and bottled drinking water (see section 3.1.7) are listed in Schedule 1, and make independent provision for a Government Chemist function. Also listed are the Poultry Meat (Water Content) Regulations 1984 (SI 1145), which provide in a distinct form of words for counter-analysis by the Government Chemist.

¹⁷ This term is used to mean England, Scotland, Wales, and Northern Ireland.

¹⁸ 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.

¹⁹ The Official Feed and Food Controls (Scotland) Regulations 2010 (SSI 5) corrected defects in SSI 2009/446, including an internal reference to the regulation which covers sampling.

²⁰ 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*.

²¹ EU legislation is evolving rapidly in this area. Regulation (EU) No 878/2010 amended Annex I of Regulation 669/2009 to set the frequencies of checks for aflatoxins, heavy metals, pesticides, ochratoxin A, salmonella, and Sudan dyes. Regulation (EU) No 1099/2010 then replaced the whole of Annex I, adjusting control frequencies up and down in the light of intelligence from RASFF (Rapid Alert System for Food and Feed), FVO (Food and Veterinary Office) inspections, and Member State quarterly reports.

The Government Chemist function is disapplied in this way from the Contaminants in Food Regulations²² too, but only to the extent that a sample falls to be prepared and analysed in accordance with the relevant EU framework Regulation²³. In practice, the Government Chemist still expects to receive samples under these regulations.

The Food Safety (Sampling and Qualifications) Regulations (Northern Ireland) 1991 (SR 198) are disapplied in the same way by entry of the corresponding legislation for Northern Ireland into their Schedule 1.

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 Regulation²⁴ 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. There are also detailed Plastic Materials and Articles in Contact with Food regulations ('plastics regulations').

Main food contact regulations

New regulations were made this year:

- The Materials and Articles in Contact with Food (England) Regulations 2010 (SI 2225), revoking SI 2007/2790
- The Materials and Articles in Contact with Food (Scotland) Regulations 2010 (SSI 327), revoking SSI 2007/471
- The Materials and Articles in Contact with Food (Wales) Regulations 2010 (SI 2288, W200), revoking SI 2007/3252, W287
- The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2010 (SR 321), revoking SR 2007/434.

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

²² 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.

²³ Regulation (EC) No 1881/2006 *setting maximum levels for certain contaminants in foodstuffs*.

²⁴ Regulation (EC) No 1935/2004 *on materials and articles intended to come into contact with food*

respectively contain specific requirements for vinyl chloride and regenerated cellulose film²⁵.

Regulation 20 of the 2010 England regulations reproduces the Government Chemist provisions from 2007, except that the gender attributions are removed and the punctuation toned down. 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 22 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

Article 5(1) of the EU food contact framework Regulation provides for the adoption of specific measures on groups of materials and articles. The most prominent among the specific measures so far adopted is a Directive on food contact plastics. National regulations applying Directive 2002/72/EC *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 tend to be revoked and remade whenever there is a change in the corresponding EU legislation. The current regulations are:

- The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 (SI 205)
- The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009 (SSI 30)
- The Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 2009 (SR 56)
- The Plastic Materials and Articles in Contact with Food (Wales) Regulations 2009 (SI 481, W49).

Taking the England regulations as an example, Regulation 3 prohibits use in the course of a business, sale, or import, for the handling of food, of a plastic material or article which fails to meet the required standard. Such failure includes manufacture with a prohibited monomer or additive. Regulation 9 sets an overall limit for migration, i.e. the transfer of constituents to food. These regulations also prescribe methods for determining the migration of specific constituents against individual limits.

Regulation 23 of the England plastics regulations names the Government Chemist and lays down a right to referee analysis (Box 3), including a defendant's right of access to secondary analysis which derives from Article 11(5) of Regulation 882/2004 (cf. section 3.1.4 of this paper). Regulation 25 continues to disapply the S&Q Regulations (see section 3.1.5 of this paper). The Government Chemist provisions for the other home countries are equivalent, *mutatis mutandis* with regard to national law.

Box 3: Plastic Materials and Articles in Contact with Food (England) Regulations 2009

Secondary analysis by the Government Chemist

23.—(1) Where a sample has been retained under regulation 22 and —

- (a) proceedings are intended to be or have been commenced against a person for an offence under these Regulations; and
- (b) the prosecution intends to adduce as evidence the result of the analysis mentioned above,

²⁵ 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.

paragraphs (2) to (7) apply.

(2) The authorised officer —

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

(b) shall —

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

(ii) if the court so orders; or

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

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

(3) The Government Chemist shall analyse the part sent under paragraph (2) and send to the authorised officer a certificate specifying the results of the analysis.

(4) Any certificate of the results of analysis sent by the Government Chemist shall be signed by or on behalf of the Government Chemist, but the analysis may be carried out by any person under the direction of the person who signs the certificate.

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

(6) Where a request is made under paragraph (2)(b)(iii) the authorised officer may give notice in writing to the defendant requesting payment of a fee specified in the notice to defray some or all of the Government Chemist's charges for performing the functions under paragraph (3), and in the absence of agreement by the defendant to pay the fee specified in the notice the authorised officer may refuse to comply with the request.

(7) In this regulation "defendant" includes a prospective defendant.

Decision 2010/169/EU *concerning the non-inclusion of 2,4,4'-trichloro-2'-hydroxydiphenyl ether in the Union list of additives which may be used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs under Directive 2002/72/EC* arises from the manufacturer's withdrawal of the application for authorisation. Plastic materials and articles manufactured with the substance may continue to be marketed until 1 November 2011. Presumably this Decision will prompt renewal of the national legislation in the new year.

In addition, the Food Standard Agency proposes to introduce Recycled Plastic Materials and Articles in Contact with Food Regulations 2011, providing for the enforcement of Regulation (EC) No 282/2008 *on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006*. The regulation of recycled materials and articles is expected to place significant new scientific demands on the Government Chemist.

Finally, the debate over Bisphenol A recently intensified, and EU legislation of limited scope has already been triggered.²⁶ Related enforcement action is likely to gain a high profile, which could lead to contested cases.

²⁶ Member States must prohibit the manufacture of polycarbonate infant feeding bottles with Bisphenol A from 1 March 2011. Placing on the market and import will be prohibited from 1 June 2011. See European Commission, Middy Express of 2010-11-26: <http://europa.eu/rapid/pressReleasesAction.do?reference=MEX/10/1126&format=HTML&aged=0&language=EN&guiLanguage=en>

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)*²⁷
- 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

In 2009, national amending regulations²⁸ implemented Directive 2009/54/EC *on the exploitation and marketing of natural mineral waters (recast)*. The most significant consequences are that natural mineral water is redefined with reference to its original purity, and microbiological requirements are clarified as applying both at source and during marketing. The changes do not affect the wording of the Government Chemist function.

Regulation (EU) No 115/2010 *laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters* requires notification of such treatment to the competent authorities, accompanied by relevant analytical results. The Annex includes the following technical requirements:

- Reagents used for initialisation and regeneration of the adsorbent to comply with relevant CEN or national purity standards

²⁷ Which repeals and replaces Directive 80/777/EEC.

²⁸ SI 2009/1598, SSI 2009/273, SR 2009/260, and SI 2009/1897 (W170).

- Activated alumina to comply with the standard for leaching tests on water treatment media - EN 12902 (2004) - to ensure, *inter alia*, that aluminium ions do not exceed 200 microgram/L (this must be checked regularly)
- GMP²⁹ and HACCP³⁰ principles set out in Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Monitoring with regard to the essential characteristics of the water and its fluoride content.

Water which has undergone fluoride removal treatment must meet a labelling requirement.

National amending regulations³¹ provide for the enforcement of Regulation 115/2010. They also insert more explicit statements on monitoring requirements for spring water and bottled drinking water for enforcement authorities. The explanatory memorandum³² states that this is just a clarification made in response to a reasoned opinion from the Commission, which asserted that the current UK implementation of Directive 98/83/EC on the quality of water intended for human consumption was not clear enough. For bottled water, the Commission was particularly concerned that monitoring frequencies be made explicit. Further amendments³³ were needed to correct certain points of the foregoing, including a concentration limit for ammonium transcribed from Directive 98/83/EC. None of the 2010 amending regulations alter the form of the Government Chemist function specified by their principal legislation, but the novel requirements relating to fluoride removal do expand our scientific scope.

3.2 Agriculture Act 1970

3.2.1 General

The Government Chemist is active in this area - typically, one or more samples are received per year 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 which 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 similar parts. One part is generally analysed by the area agricultural analyst 'or under his direction'³⁴; another

²⁹ Good manufacturing practice.

³⁰ Hazard Analysis and Critical Control Point.

³¹ SI 2010/433, SSI 2010/89, SR 2010/68, and SI 2010/748 (W76).

³² To be specific, we checked the explanatory memorandum for SI 2010/433.

³³ SI 2010/896, SSI 2010/127 and SR 2010/127.

³⁴ Appropriate precautions may be needed to show that a sample is analysed 'under his direction' if the work is subcontracted outside LGC.

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 (Box 4) 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 4: Agriculture Act 1970

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

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

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

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

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

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

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

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

(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 opinion³⁵, 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.

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 4).

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

³⁵ See section 3.1.4 above.

types (Annex I to the principal Regulation)³⁶, thereby narrowing the scope of the active referee function as regards magnesium fertilisers.

3.2.3 Animal feed

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

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

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

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

- A 'retained sample' instead of a 'remaining part'
- The taking of a sample in accordance with Regulation 152/2009, rather than 'in the prescribed manner'.

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

The Feed (Hygiene and Enforcement) (England) Regulations 2005 (SI 3280) 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 5) 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 manner³⁷ 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.

³⁶ 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).

³⁷ 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.

Box 5: Feed (Hygiene and Enforcement) (England) Regulations 2005 as amended

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 —

- (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 zotechnical 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 so as to simplify the *vires*.

Certain references to the Government Chemist have become redundant, because they are embedded in amendments to subsequently revoked regulations.³⁸

Significant EU development

Regulation (EU) No 939/2010 *amending Annex IV to Regulation (EC) No 767/2009 on permitted tolerances for the compositional labelling of feed materials or compound feed as referred to in Article 11(5)* clarifies where analytical and technical tolerances, added together, must not exceed specified percentages when testing compliance with declared values. Assuming that UK law provides for the execution and enforcement of this Regulation during 2011, we need to consider the implications speedily, and be ready to advise on the suitability of related measurements made by industry and official control laboratories.

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 6).

Box 6: 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 -

³⁸ 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).

(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)

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 MHRA³⁹ 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 years⁴⁰. The process is now moving forward from consolidation to the review proper.⁴¹ A draft of the revised text was published in August 2010, and maintained the Government Chemist provisions.⁴² Changes to the Medicines Act are unlikely to take effect before 2012.⁴³

3.3.2 Outline of the Government Chemist function

Schedule 3 Paragraph 24(1) of the Act names the Government Chemist (Box 7).

Schedule 3 ('Sampling') comes under Section 112 of the Act, which gives power to take samples for enforcement purposes. Section 112(7) enables sampling from medicinal product licence applicants. Section 113 has effect in connection with Section 112, and provides an enforcement procedure involving the Government Chemist in cases of seized materials or articles.

Schedule 3 Paragraph 1 provides that Schedule 3 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 3 Paragraph 2). One part goes to the seller (broadly speaking),

³⁹ Medicines and Healthcare products Regulatory Agency.

⁴⁰ MHRA press release, *Medicines legislation to be reviewed and consolidated by regulator*. 24 July 2008, <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON020760>

⁴¹ MHRA, web page 'Project to consolidate and review UK medicines legislation', consulted 17 December 2010: <http://www.mhra.gov.uk/Howweregulate/Medicines/Overviewofmedicineslegislationandguidance/ProjecttoconsolidateandreviewUKmedicineslegislation/index.htm>

⁴² MHRA, First draft of the consolidated medicines regulations. 27 August 2010: http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON091185&RevisionSelectio nMethod=Latest

⁴³ Crown Prosecution Service, web page 'Medicines Act 1968', published 21 June 2010: http://www.cps.gov.uk/legal/l_to_o/medicines_act_1968/

one is analysed by a laboratory recognised by the enforcement authority, and, under Schedule 3 Paragraph 10(a), one is retained for future comparison.

Section 115 provides for the purchaser of a medicinal product to submit a sample to the public analyst. In accordance with Section 115(2), the purchaser is to apply part of Schedule 3, including Paragraphs 2 and 10(a) which provide scope for exercise of the Government Chemist function.

Under Schedule 3 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 7: Medicines Act 1968

SCHEDULE 3 SAMPLING

24.—(1) In any proceedings for an offence under this Act, where the proceedings relate to a substance or article of which a sample has been obtained as mentioned in paragraph 1 of this Schedule, the part of the sample retained in pursuance of paragraph 10(a) of this Schedule shall be produced as evidence; and the court—

- (a) at the request of either party to the proceedings shall, and
- (b) in the absence of any such request may if it thinks fit,

cause that part of the sample to be sent for analysis to the Government Chemist (or, in Northern Ireland, the Government chemist for Northern Ireland*) or to be sent for other appropriate examination to the person having the management or control of a laboratory specified by the court.

* 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 (LBRO) indicates that local authorities are most likely to enforce the Act through their trading standards services⁴⁴. 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 8). Under Section 4(5), an appeal court can do this if it has not yet been done.

Box 8: 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 Wales⁴⁵, the Plant Protection Products (Scotland) Regulations 2005 (SSI 331)⁴⁶, and the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (SI 716); these extend to Great Britain⁴⁷. Samples have not been received under the 1967 Act in recent years.

⁴⁴ 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

⁴⁵ 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.

⁴⁶ In accordance with regulation 28(3) thereof; the arrangement of relevant provisions is similar to SI 2005/1435.

⁴⁷ 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

Regulation (EU) No 915/2010 *concerning a coordinated multiannual control programme of the Union for 2011, 2012 and 2013 to ensure compliance with maximum levels of and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin* takes forward the wide-ranging EU surveillance scheme established in 2009. The analytical requirements apply to defined groups of foods, and in many cases, related compounds such as isomers and metabolites must be reported.

Regulation (EU) No 1141/2010 *laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances* requires limited data to help with substance identification, including on any variants produced, such as salts, esters or amines, and on purity in g/kg. Analytical details are not required. This renewal covers 31 active substances for plant protection products, and requires the latest scientific and technical knowledge to be taken into consideration.

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 9. 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 9: Hydrocarbon Oil Duties Act 1979

SCHEDULE 5

SAMPLING

2.—(1) The result of an analysis of a sample shall not be admissible—
in criminal proceedings under the Customs and Excise Acts 1979; or
on behalf of the Commissioners in any civil proceedings under those Acts,
unless the analysis was made by an authorised analyst ...

5. In this Schedule "authorised analyst" means—

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

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

4.1.2 Recent developments

The following new legislation may impact on the Government Chemist functions in the 1979 Act:

- The Biodiesel Duty (Biodiesel Produced from Waste Cooking Oil) (Relief) Regulations 2010 (SI 984) preserve the 20 pence per litre duty incentive for biodiesel produced from waste cooking oil until 31 March 2012. For other biofuels, the duty differential was withdrawn from 1 April 2010 because a more sophisticated approach - the Renewable Transport Fuels Obligation - is now in place with the aim of ensuring that only sustainable products are

promoted. Analysts could be called on to confirm that biodiesel samples are produced from waste cooking oil, as against biomass-based biodiesel or even non-waste cooking oil. But HMRC is relying mainly on paper-based evidence of compliance - for example, a Waste Transfer Note.⁴⁸ Meanwhile, a rebated rate of duty remains in force for off-road biodiesel

- As mentioned last year, the maximum concentration of EN 14214-compliant fatty acid methyl esters (FAME) in diesel has risen from 5 to 7 % by volume. The Biofuel (Labelling) (Amendment) Regulations 2009 (SI 3277) apply the consumer information requirements of Directive 2009/30/EC by raising the threshold for special fuel pump labelling to 7 % biodiesel. Analytical methods which are optimised for this threshold could be required to resolve disputes over the specification supplied to the consumer. We can address any requirements by building on established Government Chemist methods compatible with up to 20 % biodiesel or vegetable oil
- Since the EU introduced anti-dumping and countervailing measures on imports of biodiesel from the USA (Regulations (EC) No 599/2009 and 598/2009 respectively), evidence has emerged that shipments are being re-routed via Canada and Singapore. Moreover, consignments from the USA are apparently being blended down to 20 % biodiesel or less, to circumvent the current EU threshold. For both types of imports, new Commission Regulations - (EU) Nos 720/2010 (re anti-dumping measures) and 721/2010 (re countervailing measures) initiate an investigation, and require customs declaration of the total proportion of biodiesel by weight. The new Regulations both define biodiesel as 'fatty-acid mono-alkyl esters and/or paraffinic gasoil obtained from synthesis and/or hydro-treatment, of non-fossil origin'. If laboratories are called upon to support enforcement, they may need to build up experience with chemical markers of particular synthetic and hydro-treatment processes, because the major constituents of such products could be difficult to distinguish from those of fossil origin
- The Hydrocarbon Oil Duties (Marine Voyages Reliefs) (Amendment) Regulations 2010 (SI 2868) accept the practice of claiming duty relief on marine fuel at some point up the trading chain, rather than only at the point of supply. This decision aims to relieve regulatory burdens, but we may need to be aware in case the illegal diversion of duty-relieved fuel intended for use on ships becomes an issue.

⁴⁸ HMRC, Excise duty: relief scheme for biodiesel produced from waste cooking oil. Revenue & Customs Brief 18/10, 29 March 2010: <http://www.hmrc.gov.uk/briefs/excise-duty/brief1810.htm>

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 on account 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'.

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 rules⁴⁹ 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 on the grounds that 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 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.

⁴⁹ The Poisons Rules 1982 (SI 218) as amended.

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)⁵⁰, 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 liferaft equipment (Box 10).

Box 10: 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)⁵¹ 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)⁵², 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).

⁵⁰ <http://www.mcga.gov.uk/c4mca/mcga-mlid-page.htm?textobjid=220A9D3228EC6C52>

⁵¹ 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).

⁵² Our contact on 24 February 2006 was with MCA's Lifesaving Appliances Policy Manager.

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.

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 1998.⁵³ 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 11) - which suggests that they were saved for good reason.

⁵³ 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>

Box 11: Administrative Provisions Act (Northern Ireland) 1928

Provisions as to Government Chemist for Northern Ireland

2. —

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

[Subsection (2) repealed.]

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

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

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

Subsection 2(5) of the 1928 Act makes reference to Section 63 of the Government of Ireland Act, 1920, which did not name the Government Chemist but generally allowed for the Great Britain and Ireland (including Northern Ireland) authorities to make arrangements for the exercise and performance of powers and duties by each other's officers - provided that the authority making the arrangements remained fully responsible. The 1920 Act was repealed by Section 2 of the Northern Ireland Act 1998. However, the Government Chemist Regulations (Northern Ireland) 1928 (No. 104), made under Section 2 of the 1928 Act, clarify the appointment (Box 12).

Box 12: 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 Ireland⁵⁴. 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.

⁵⁴ 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.'

6.3.2 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'.

6.4 Commonwealth

Over the last two 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 2010, there have been no major changes to the legislative scope of the Government Chemist statutory functions. However, there have been a number of interconnected changes to feed law, reflecting attempts to consolidate and ease regulatory burdens at 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 Food Safety (Sampling and Qualifications) Regulations 1990 are central to the exercise of the Government Chemist referee function in most cases arising under the Food Safety Act 1990. The Food Standards Agency review of the 1990 regulations, to align them with Regulation (EC) No 882/2004 *on official controls* and with other EU Member States, has been rescheduled and is currently expected to start in April 2011.⁵⁵

During 2011, 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 2008-11. In the new programme, we recommend that:

1. This paper continues to be updated every year. Experience has shown that if the process lapses, greater efforts will eventually be needed to rescue it
2. Responsibility for its upkeep is clearly assigned by means of a transferable title such as 'Government Chemist Scope Holder'
3. The post holder gains a working knowledge of the task by reviewing references to the Government Chemist on the National Archives website, and checking our research on repeals and revocations, to verify that our understanding of the extant statutory functions is complete
4. In the past, this area of work has extended to legislation that does not specifically mention the Government Chemist, but under which that authority, or LGC, may be called upon to carry out analyses.⁵⁶ It may be useful to NMO and other stakeholders if we update that work by collating all the legislation which is currently being supported by the LGC Science and Technology division.

More generally, to add value to UK plans for innovation-based industrial resurgence, the vision for our remit might usefully take a rounded view of the varied parts played and problems solved by the Government Chemist and his laboratory since 1842.⁵⁷

⁵⁵ FSA, *Proposed consultations*. Consulted 20 December 2010:
<http://www.food.gov.uk/multimedia/webpage/propconsult>

⁵⁶ Dietz R, *The Government Chemist*. Revised ROAME paper, 18 January 1995.

⁵⁷ Cf. Hammond PW and Egan H, *Weighed in the balance*. HMSO, 1992, ISBN 0 11 515302 0.