

Government Chemist 2005-2008 Programme

Review of Changes in UK Food
and Feed Legislation
April 2005 to March 2006

May 2006

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*Setting standards
in analytical science*

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and Feed Legislation
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1 Summary

This report describes the 24 new pieces of UK legislation in the food and agriculture sector that have occurred between April 2005 and March 2006). These are shown in tabular form in Appendix I. The most important developments with relevance to measurement science are measures introduced as a result of Regulation (EC) 882/2004, a framework regulation to harmonise levels of food and agriculture enforcement throughout the community. This instrument, together with more specific legislation at European level widens the requirements relating to sampling, analysis and interpretation for official feed and food control, especially in relation to food contaminants and undesirable substances in animal feed.

2 Foreword

This is the first of three reviews to be undertaken as part of the project RF1 (Milestone RF1/3a) in the Government Chemist 2005-2008 programme. It covers changes in UK food and agricultural legislation that have taken place during the period April 2005 to March 2006 and are important to stakeholders in food control, especially those that relate to chemical measurement and the role of the Government Chemist.

Since this is the first report, it was thought useful to provide, at the same time, some background to the legislation to show why, as well as how, it has changed and to provide an insight into the reasons for the existence of statutes in the areas covered.

The Office of Public Sector Information ([OPSI](#)) and European legislative information database, [Eur-Lex](#), websites have been used as the information sources on which the report is based. In each case, the English regulations have been cited, though equivalent regulations have been made at the same time for Scotland and Wales.

3 Introduction

Since the formation of the European Food Safety Authority in 2002, there has been considerable activity at European level in the area of food safety and the introduction of harmonised controls over the whole of the food chain including agricultural production and primary products. Almost all of the UK legislation made in the last year has been as a result of these European instruments, be they Regulations, Directives or Decisions.

In this report, each change has been considered in terms of the purpose of the regulation, the background to it, and a summary of the provisions together with some comments and how it may affect the Government Chemist function. Further detail of the provisions is available through hyperlinks to the original European instrument to which the UK legislative changes give effect.

4 The Official Feed and Food Controls (England) Regulations 2005 ([2005 No.2626](#))

4.1 Purpose

This instrument provides for the execution and enforcement of the feed and food elements of EU Regulation [882/2004](#) on official feed and food, animal health and animal welfare controls. It designates the competent authorities and enforcement authorities and creates relevant offences and penalties. In particular, it provides for the enforcement of new rules on official controls of feed and food of non-animal origin imported from outside the Community.

4.2 Background

The EU Regulation sets out a framework of requirements for the authorities in Member States (the competent authorities) that are responsible for monitoring and enforcing compliance of businesses with feed and food law (i.e. for undertaking official controls) as well as for checking that animal health and animal welfare rules are adhered to. This framework includes the principles that should be adopted, e.g. a risk-based and 'farm to fork' approach, and specifies operational criteria with which the authorities must comply, e.g. they must be audited to assess the effectiveness of their performance. The Regulation also includes new harmonised rules for official controls of feed and food of non-animal origin imported from third countries, i.e. those outside the European Union.

The provisions of the EU Regulation apply directly in the Member States. Most of these consolidate existing requirements such that enforcement arrangements in the UK for feed and food are generally already consistent with them. However, some updating is needed. In particular, national legislation was needed to extend the Food Standards Agency's existing function (set out in the Food Standards Act 1999) to monitor and audit enforcement authorities. Additionally, the specific requirements for checks of third country imports of feed and food of non-animal origin were new and national legislation was needed to provide for their enforcement.

The objective of the EU Regulation is to create a more comprehensive and integrated, risk-based, 'farm to fork' approach to official controls. It does so by consolidating and extending existing legislative requirements. The aim is to improve the consistency and effectiveness of controls across the EU and, as a consequence, raise standards of food safety and consumer protection. The EU Regulation also aims to provide a greater degree of transparency for consumers about enforcement arrangements. The national legislation provides the enforcement powers required in relation to provisions in the EU Regulation that have applied since 1 January 2006 and contributes to the anticipated benefits of a more consistent and effective control system.

4.3 Comments on the legislation

The majority of comments received in response to the statutory consultation related to the provisions in the statutory instrument on import controls for feed and food of non-animal origin from third countries.

The only significant objection from stakeholders was with regard to the role envisaged for Her Majesty's Revenue and Customs (HMRC) in import controls. Following initial discussions, it had been envisaged that HMRC would be involved in undertaking documentary checks of consignments (examination of commercial documents and documents required under feed and food law). However, on further consideration, HMRC concluded that customs officers do not have the necessary

technical expertise to undertake this function. This view was strongly supported by enforcement stakeholders and has been accepted by the Food Standards Agency. These checks will instead continue to be undertaken as now by local and port health authorities. This approach also acknowledges concerns expressed by industry stakeholders regarding potential for duplication of effort and confusion about the role of HMRC and that of local and port health authorities.

Another major concern of stakeholders was the need generally for co-operation and co-ordination between enforcement authorities to avoid duplication and to ensure consistency of approach, particularly with respect to import controls. This was acknowledged and the need for partnership working to achieve this was recognised. In this respect, the Agency will continue to work closely with HMRC, the UK Agriculture Departments and with local and port health authorities to ensure that imported food controls are in place at borders and inland. This will build on and aim to strengthen existing avenues of communication and co-operation, which are already well developed.

4.4 Effects

This Statutory Instrument gives effect to the provisions of Regulation 882/2004 for official control, some of which have a direct bearing on analytical measurement.

The general provisions in Article 11 are that sampling and analysis must be carried out according to community rules. If no such rules exist they must comply with internationally recognised rules or protocols, for example those that the European Committee for standardisation (CEN) has accepted or those agreed in national legislation. In the absence of either of the above they must be fit for the intended purpose or developed in accordance with scientific protocols. Where validated methods do not exist, methods may be validated in a single laboratory according to an internationally accepted protocol. In addition, it provides in Annex III criteria by which analytical methods used for food control should be characterised. Finally, it enables further implementing measures to be taken by the Commission (using the committee procedure referred to in Article 62(3)) to specify methods of sampling and analysis, performance criteria, and interpretation of results.

The Regulation also requires at Article 11 that the competent authorities must establish adequate procedures 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. This is implemented in the UK regulation by reference to the existing Food Safety (Sampling and Qualifications) Regulations 1990, which provide for the third part of the sample to be submitted to the Government Chemist.

Article 12 of the Regulation requires that analysis for official control be carried out in laboratories designated by the competent authority and that the authority can only designate those that are accredited to the ISO 17025 standard (see below).

The Government Chemist, and most public analyst laboratories in UK, already comply with the above general requirements in relation to analysis for food control, since they reflect good analytical practice and some of them were already required by the “additional measures directive” [93/99](#), now revoked. There are, however, some laboratories in UK that are not yet accredited for agricultural analysis.

There may be some conflict between the current conditions under which a sample can be submitted to the Government Chemist, as set down in the Food Safety (Sampling and Qualifications) Regulations 1990 and the wording of Article 11 of the

EU regulation and this is under discussion at the time of writing with the Food Standards Agency.

5 The Official Feed and Food Controls (England) Regulations 2006 ([2006 No. 15](#))

The 2005 regulations (see immediately above) were in force for just 11 days before being revoked and re-enacted by the 2006 regulations. The reason for this was that several relevant new EU regulations were published in the Official Journal very shortly after SI 2006 No.15 came into force.

There are two reasons for these legislative changes, both of which are derived from the adoption of a number of new Commission Regulations, which include transitional and implementing measures relating to Regulation 882/2004 (Regulation (EC) [2076/2005](#)) (as well as to new EU legislation on food hygiene). These measures:

- extend the period allowed for certain official laboratories to meet required European standards, and
- specify requirements for Member States regarding publication of lists of approved food business establishments.

5.1 Effects

The effect of interest to official laboratories is that they are not required to achieve accreditation to ISO 17025 (see above) until 31 December 2009, providing that they can demonstrate to the competent authority that they have begun the process and have quality systems in place for the analytical work that they do for the purposes of official control.

6 The Food Hygiene (England) Regulations 2005 (2005 No. 2059) and The Food Hygiene (England) Regulations 2006 ([2006 No. 14](#))

6.1 Purpose

This Statutory Instrument provides enforcement powers in respect of the EU Food Hygiene Regulations and associated pieces of implementing and transitional legislation. In particular, it designates competent authorities and enforcement authorities and makes provision for offences and penalties. It also addresses aspects where the EU Regulations either require or allow Member States to adopt certain provisions in their national law.

As was the case for the Official Feed and Food Controls (England) Regulations, the 2005 regulations were in force for just 11 days before being revoked and re-enacted by the 2006 regulations. The reason for this was the timing of the publication of the related EU regulations in the Official Journal.

6.2 Background

The new EU legislation (Regulations [852/2004](#), [853/2004](#), [854/2004](#), [2073/2005](#) and [2075/2005](#)) has as its primary objective the optimisation of public health protection by improving and modernising the previous sector specific EU legislation. It establishes

the conditions under which food is produced to prevent, eliminate or acceptably control pathogen contamination of food. More risk-based and flexible procedures are introduced that are better matched to the needs of individual businesses and to enforcement. The legislation introduces a "farm to fork" approach to food safety, by including primary production in food hygiene legislation for the first time in the majority of cases. Regulation 852/2004 lays out general hygiene requirements for food businesses. These are supplemented by regulation 853/2004 which relates more specifically to products of animal origin and regulation 854/2004, which relates to official controls for products of animal origin.

The EU Food Hygiene Regulations are directly applicable in each Member State of the EU. National legislation is neither required nor allowed, to give effect to the EU Regulations, beyond providing for their enforcement in England. However, there are a number of areas where the EU Regulations either require or allow Member States to adopt certain provisions in their national law and the UK Regulations address those aspects too.

As the subject matter of the SI is food hygiene it has been developed to mirror the provisions of the Food Safety Act 1990. The regulations create penalties and offences, powers of entry and other administrative measures based in the main on existing requirements. Where the EU Regulations do not apply and no more specific national provisions have been made, the provisions of the Food Safety Act 1990 apply to ensure the supply of food in such circumstances is fit for human consumption.

6.3 Effects

The Regulations designate the Food Standards Agency as the competent authority and designate food authorities and the Food Standards Agency as enforcement authorities. The division of responsibility is set out in the regulations.

Whilst the regulations mostly relate to food hygiene requirements in food production and supply, they also make specific reference to procedures required for sampling for analysis or examination (meaning microbiological examination). These requirements are the same as those in the [Food Safety Act 1990](#), as amended and make reference to the [Food Safety \(Sampling and Qualifications\) Regulations 1990](#), as amended. The role of the Government Chemist is not affected by any of the provisions of the legislation.

7 The Contaminants in Food (England) Regulations 2005 ([2005 No. 3251](#))

7.1 Purpose

These Regulations, made under The Food Safety Act 1990, as amended, make provision for the execution and enforcement of European Community measures setting maximum levels for certain contaminants in foodstuffs and implement allied European Commission Directives concerning sampling and analysis. They specify, by reference to the European Directives rules for methods of sampling and analysis for a range of contaminants. The Regulations revoke and replace The Contaminants in Food (England) Regulations 2004 (SI 2004 No 3062) as amended by The Contaminants in Food (England) (Amendment) Regulations 2005 (SI 2005 No 775).

The European Community measures are Commission Regulation (EC) No. [466/2001](#), which has been amended many times, the most recent of which are by various new European Community (EC) Regulations setting maximum levels for ochratoxin A, nitrate and polycyclic aromatic hydrocarbons (PAHs) in certain foodstuffs. They also revise the existing EC maximum levels for heavy metals (lead, cadmium and mercury) in fish.

7.2 Background

Commission Regulation (EC) No. 466/2001 of 8 March 2001 sets maximum levels for certain contaminants in foodstuffs and has applied since 2002. It is supported by a number of enforcement Commission Directives, which lay down the methods for sampling and analysis for the official control of those contaminants specified in the legislation. In England provision for the enforcement and transposition of these measures was under The Contaminants in Food (England) Regulations 2004, as amended.

EC legislation on contaminants is made under the framework Regulation for food contaminants, Council Regulation (EEC) [No 315/93](#) of 8 February 1993. The Regulation lays down Community procedures for contaminants in food and applies to those contaminants that are not covered by other specific Community legislation. Article 2 to the Regulation provides that food containing a contaminant in an amount that is unacceptable from the public health viewpoint, and in particular at a toxicological level, shall not be placed on the market. Paragraph 3 to the article requires that maximum levels must be set for specific contaminants and that these levels must be adopted in the form of a non-exhaustive Community list. In view of disparities between the laws of Member States in regard to the maximum levels for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Community measures (Commission Regulation (EC) No 466/2001 of 8 March 2001) were introduced under Council Regulation 315/93/EC.

The intention of Commission Regulation 466/2001 was to provide consumers with an increased measure of protection by setting maximum levels for mycotoxins and undesirable process and environmental contaminants in those foodstuffs that are significant contributors to the total dietary exposure of consumers. The Regulation, which has undergone a large number of amendments, aims to keep contaminants at levels that are toxicologically acceptable and to exclude grossly contaminated food from entering the food chain. It also harmonises Member States' existing measures, thus facilitating trade. Maximum levels for lead, cadmium, mercury, dioxins and nitrate (environmental chemical contaminants), 3-MCPD (a process contaminant), aflatoxins, ochratoxin A and patulin (mycotoxins) and inorganic tin have already been set under this legislation.

In view of the requirement to protect public health by keeping contaminants at levels that are toxicologically acceptable, the European Commission, in co-operation with member states, investigates whether limits should be set for additional contaminants and also reviews the maximum limits of those contaminants currently in the legislation. As a result, Commission measures, which amend Commission Regulation 466/2001, have been adopted and provision has been made in the Statutory Instrument for their enforcement and implementation as described below.

7.3 Effects

The new regulations introduce the requirements of the following European legislation into UK law:

- Commission Regulation (EC) No [123/2005](#) setting maximum levels for ochratoxin A in certain foodstuffs. This Regulation is supported by Commission Directive [2005/5/EC](#) amending Directive [2002/26/EC](#) which lays down sampling methods and methods of analysis for the official control of the levels of ochratoxin A in certain foodstuffs
- Commission Regulation (EC) No [78/2005](#) revising the current maximum levels for lead cadmium and mercury in fish.
- Commission Regulation (EC) No [208/2005](#) of 4 February 2005 setting maximum levels for the PAH, benzo(a)pyrene, in certain foodstuffs. This Regulation is supported by Commission Directive [2005/10/EC](#) for methods of sampling and analysis for benzo(a)pyrene.
- Commission Regulation [1822/2005](#) amending the time periods during summer and winter to which maximum limits apply for nitrate in fresh spinach. It also extends the derogation period for certain Member States including the UK whereby fresh spinach and fresh lettuce are exempt from the limits when produced and placed on the market in the country to which the derogation applies.
- Commission Directive [2005/4/EC](#), which supports Commission Regulation 466/2001 by amending Directive [2001/22/EC](#) which lays down methods for sampling and analysis for the official control of lead, cadmium, mercury and 3-MCPD in foodstuffs. The Directive includes updated analytical information and requirements and applies specifically to public analysts and those laboratories accredited to carry out official control work, including the Government Chemist.

The Contaminants regulations have an impact on official control laboratories in that they must be capable of detecting and quantifying the residues at the levels specified in the regulations and using methods of analysis that have the required demonstrable performance characteristics. Additionally, they must take into account recovery and uncertainty when assessing whether samples received comply with the limits set by the regulations. The contaminants area is one of the first where analytical quality requirements have been agreed by the committee procedure laid down in Article 62(3) of Regulation (EC) 882/2004 and taken into account for food control purposes.

7.4 Comments on the legislation

There were 4 substantive responses, mainly from enforcement authorities and industry, to the formal consultation process. Of these, four were substantive and indicated the need for simplification of the Regulations. Following these comments the draft Regulations were revised to simplify certain aspects of the text whilst remaining within the remit of accurately enforcing and implementing the Community measures.

Swordfish, in particular the larger fish were unable to comply with the existing maximum levels for cadmium in fish. Although little quantified information was submitted, importers indicated that this was having a significant detrimental effect on the industry. Also of concern was the long-term sustainability of this species, as, in order to comply, smaller, younger fish would be taken. The UK successfully negotiated a higher level, which went some way to addressing industry's concerns whilst continuing to maintain a high level of consumer protection and choice and helping to promote the sustainability of swordfish.

Comments from the proposals for PAH varied, with some respondents indicating general support for maximum levels and others indicating opposition to either a specific proposed level and/or a specific food category to be included in the legislation. Although there is little recent data available, industry indicated that the initial proposals for shellfish would have a significant negative impact on the industry with the possible loss of livelihood of those employed in certain regions in England and Wales. The UK successfully negotiated an interim higher level for bivalve molluscs only. This level will be revised when further data become available.

As a consequence of industry consultation on new limits to be set for ochratoxin A and discussions at the Commission, limits for soluble coffee were renegotiated and the inclusion of other fruit juices and other alcoholic beverages was withdrawn from the Regulation. In addition, the setting of certain limits for other commodities such as spices and cocoa has been deferred until more data are available.

8 The Materials and Articles in Contact with Food (England) Regulations 2005 ([2005 No. 898](#))

8.1 Purpose

This instrument invokes Regulation (EC) No. [1935/2004](#) which came into force on 3 December 2004 and revokes EC Directive 89/109/EEC. It revises the penalties that may be applied for infringements of that Regulation. It also revokes the parts of The Materials and Articles in Contact with Food Regulations 1987 (1987 No 1523) that were made to give force to Directive 89/109/EEC, now revoked, but re-enacts the provisions from the 1987 regulations that should remain in force. Finally, it implements Directive [2004/14/EC](#), which brings up to date the European harmonised rules relating to the manufacture of materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.

The Materials and Articles in Contact with Food Regulations 1987, and the 1994 amending Regulations (1994 No. 979) implemented Council Directive [89/109/EEC](#) on materials and articles intended to come into contact with foodstuffs; Council Directive [78/142/EEC](#) relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs, and Commission Directive [93/10/EEC](#), as amended by Directive [93/111/EC](#), on materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.

Council Directive 89/109/EEC was revoked by Regulation (EC) No. 1935/2004. However, as Council Directive 78/142/EEC and Commission Directives 93/10/EEC and 93/111/EC remain in force, those parts of the 1987 Regulations that had implemented them in England are re-enacted in this instrument.

8.2 Background

It is the intention that the law on materials and articles intended to be brought into contact with food should protect human health from the chronic effect over a person's lifetime of the consumption of food contaminated with chemicals used in the manufacture of the materials and articles. The principle purpose of the restrictions imposed on the use of the chemicals to which restrictions apply is to minimise the risk to consumer health from exposure to chemicals that may be carcinogenic, mutagenic or toxic to reproduction. The law also aims to protect the nature and quality of the food concerned and to provide businesses in the industry with one set of harmonised rules that apply throughout the EU, instead of a plethora of different

national rules in each EU Member State. One of the principal changes brought about by the European Regulation is that it allows for the same rules to apply across the EU. The Regulation also, for the first time permits for intended migration of substances by regulating the use of 'active' and 'intelligent' materials and articles, which are designed to interact with the food.

The European Commission, taking account of the opinions of the European Food Safety Authority on the use of these substances, routinely amends technical lists of substances that contain conditions on their use in the manufacturing process. Substances that are deemed to cause unacceptable risk to consumer health, particularly among vulnerable people, may be prohibited from use. Member States and industry at European and national level were fully consulted about these proposals and they were in line with Government policy to reduce the risk to consumers of exposure to a minimum.

Regulation 2004/14/EC takes into account the technological developments that have taken place since the adoption of the original Directives in 1993. These include the fact that three substances in the phthalates group are no longer used by the industry and can be removed from the positive list. The authorisation of regenerated cellulose film accords with European environmental requirements laid down in adopted measures on packaging waste.

8.3 Effects

This statutory instrument designates, at regulation 12, the authorities having the responsibility to enforce the EC Regulation, and provides for that enforcement by prescribing the penalties that the Courts may impose on conviction for an offence under the Regulation. These penalties are in line with those that apply under other food-related law through the Food Safety Act 1990.

Some provisions in the 1987 Regulations implemented EC measures on vinyl chloride monomer and regenerated cellulose film and those provisions are re-enacted by this instrument.

Commission Directives 93/10/EEC and 93/111/EC cited above established a positive list of substances that can be used in the manufacture of coated and uncoated regenerated cellulose film. Some of the substances in the positive list have conditions restricting their use in the manufacture of these food contact materials. In particular, uncoated film must not transfer adhesives or colourants in detectable quantities, and coated film must not transfer ethylene glycol or di(ethylene) glycol, by themselves or together, in quantities exceeding 30 milligrammes per kilogramme of food. Synthetic casings made of regenerated cellulose films that have coatings on the food contact side of greater than 50 milligrammes per square decimetre of film are, at present, excluded from the scope of the legislation.

This latest Commission amending Directive, 2004/14/EC, amends Directive 93/10/EEC and provides that uncoated, cellulose coated and plastic coated regenerated cellulose film intended for food contact applications are subject to the conditions laid down and to manufacture from only the substances listed. It also applies the conditions laid down in Directive [2002/72/EC](#) on plastic materials and articles intended to come into contact with foodstuffs, to those regenerated cellulose films coated with plastics.

9 Colours in Food (Amendment) (England) Regulations 2005 ([2005 No.519](#))

These regulations were made to implement the provisions of Commission Directive [2004/47/EC](#), which itself amends, for the third time, Commission Directive [95/45/EC](#), which sets out specific purity criteria (specifications) for individual approved food colours.

This amendment incorporates recent advice from the European Commission's Scientific Committee on Food (SCF) (now the European Food Safety Authority's Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food) to bring the specifications for mixed carotenes, E160 a (i) and beta carotene E160 a (ii), into line with international standards. In particular, the specification for beta-carotene from *Blakeslea trispora* (E160 a (ii)) has been amended to include two additionally permitted extraction solvents (isobutyl acetate and isopropyl alcohol). Levels for heavy metals in the specifications for mixed carotenes (E 160a(i)) and beta-carotene (E160 a(ii)) have been amended to bring them into line with international standards.

9.1 Background

Commission Directive 95/45/EC forms part of a continuing programme to update EU wide specifications for food colours which are used to ensure the purity, and hence the safety to consumers, of these substances.

9.2 Effects

The amendments have little effect on official laboratory requirements since capabilities already exist for the determination of heavy metals and residual solvents.

10 The Smoke Flavourings (England) Regulations 2005 ([2005 No. 464](#))

10.1 Purpose

This new regulation introduces requirements for safety assessment and authorisation of primary products and/or derived smoked flavourings intended for use in or on foods. It is made to provide enforcement powers for Regulation (EC) No. [2065/2003](#) relating to smoke flavourings used or intended for use in or on foods. (The validity of the Treaty base of the EC Regulation is at the time of this report being challenged before the European Court of Justice by the United Kingdom Government).

10.2 Background

Regulation (EC) No. 2065/2003 establishes Community procedures for the evaluation and authorisation of primary products from which smoke flavourings may be made, lays down the conditions for their production and the information necessary for their evaluation. Smoked foods produced using traditional smoking processes are not affected. The new Regulations apply to both manufacturers of primary products and/or smoke flavourings and food producers who use smoke flavourings in their products. The use of smoke flavourings in the UK has until now simply been subject to the general requirements of UK Food Law.

Although there are no known UK manufacturers of smoke flavourings at present, the Food Standards Agency, as designated competent authority, is in a position to receive applications from any manufacturer who wishes to have their products evaluated and authorised.

10.3 Effects

The key elements of Regulation (EC) No. 2065/2003 are:

- to specify the information necessary for the scientific evaluation and authorisation of primary products to be conducted by the European Food Safety Authority (EFSA) according to a transparent procedure within a specific timeframe,
- to produce a positive list of primary products and specify their conditions of use in or on foods,
- to require approved products to be re-submitted for evaluation and renewal of the authorisation at 10-yearly intervals,
- to place traceability requirements on businesses involved in sale of authorised smoke extracts or flavourings derived from such extracts.

The legislation has no impact on the official laboratory or Government Chemist function.

11 The Miscellaneous Food Additives (Amendment) (England) Regulations 2005 ([2005 No. 1099](#))

11.1 Purpose

These Regulations implement the provisions of European Parliament and Council Directive [2003/114/EC](#), which itself amends, for the fifth time, European Parliament and Council Directive [95/2/EC](#).

Council Directive 95/2/EC forms part of the Single Market initiative on the use of additives in the European Union and ensures consumer protection measures are in place in relation to miscellaneous additives. It sets out a list of authorised miscellaneous additives, the foodstuffs in which they may be used and their conditions of use.

11.2 Effects

The amending Directive, 2003/114/EC, has been made to incorporate recent technical and scientific developments in relation to miscellaneous additives:

- the authorisation of one new food additive, hydrogenated poly-1-decene (E 907) for use as a glazing agent for sugar confectionery and dried fruits, and a number of new food uses for currently permitted food additives;
- the clarification or extension of certain food categories in which permitted miscellaneous food additives may be used, and the introduction of alternative names - cellulose gum and enzymatically hydrolysed cellulose gum - for E 466 (carboxy methyl cellulose and E 469 (enzymatically hydrolysed carboxy methyl cellulose) respectively;
- the deletion of one food category (cider and perry) from the foods permitted to contain phosphates (E 338 – 452);

- the introduction of numerical maximum limits for uses of carnauba wax (E 903) following recent advice from the Scientific Committee on Food. This was previously permitted to be used at *quantum satis* level (i.e in line with good manufacturing practice);
- the extension of the scope of the existing food additive category of stabilisers to cover binding agents.
- the introduction of harmonised controls on additives needed for the storage and use of flavourings. At present, different laws apply in individual Member States to these substances, with no specific controls existing in the UK, although any substance added to food must meet the general requirements of the Food Safety Act 1990.

11.3 Comments on the legislation

A number of flavourings companies, via their trade organisation the British Essence Manufacturers' Association, have claimed that the necessary reformulation of flavouring preparations is likely to result in quite substantial costs.

Manufacturers were not required to withdraw products not complying with the provisions of the Directive until January 2006, as an aid to reducing the negative impact of any reformulation costs. It is, moreover, normal industry practice to routinely reformulate flavouring products to improve consumer acceptability, cost effectiveness etc.

12 The Food (Chilli, Chilli Products, Curcuma and Palm Oil) (Emergency Control) (England) Regulations 2005 ([2005 No.1442](#))

12.1 Purpose

This Statutory Instrument maintains and extends in England the existing import controls on the presence of specific Sudan dyes in foods to include palm oil and turmeric (curcuma). The Food (Hot Chilli and Hot Chilli Products) (Emergency Control) (England) Regulations 2003 (S.I. 2003/1940) (as amended), which implemented all existing European legislation in this area are revoked and remade by the SI, which implements [Commission Decision of 23 May 2005](#) on emergency measures regarding chilli, chilli products, curcuma and palm oil and itself repeals and extends Commission Decision 2004/92/EC on emergency measures regarding hot chilli and hot chilli products.

12.2 Background

Commission Decision [2004/92/EC](#) requires that consignments of chilli, chilli products and curry powder imported into the European Community must be accompanied by a certificate showing that they have been tested and are free from the industrial dyes Sudan I – IV. The Sudan dyes are considered genotoxic carcinogens and their presence in food at any level is unacceptable. Should the product be found to contain any of the dyes, or the importer is unwilling for it to be tested, it must be destroyed.

At a meeting of the Standing Committee on the Food Chain and Animal Health on 4 April 2005, Member States adopted a Commission Decision that would extend the

existing controls on the presence of Sudan dyes to two further foodstuffs – palm oil and turmeric. Sudan IV has recently been found in the UK and other Member States in consignments of raw palm oil from certain West African countries. These oils are intended to be used, for example, in West African cuisine. The controls on turmeric were introduced following the discovery of two contaminated batches, in Spain and Cyprus, in November 2004.

Due to the need to implement these emergency provisions urgently, given the seriousness of the health threat to consumers, no formal consultation has been carried out on the new legislation, although relevant industry contacts were notified and their views taken into account in developing the provisions of the Decision.

12.3 Effects

Consignments of dried and crushed or ground turmeric intended for human consumption and palm oil intended for direct human consumption imported into the EU must be tested and accompanied by a certificate stating they are free of specified Sudan dyes. Consignments of palm oil that are destined for further processing are exempt from these requirements, however. An additional requirement has also been introduced that will require all certificates of analysis accompanying consignments of any products controlled by the Decision to be endorsed by the competent authority in the exporting country.

12.4 Comments on the legislation

Consignments of the products covered by the legislation must be tested for the presence of the dyes mentioned by the official laboratories of the competent authorities of the importing member states. Unlike the requirements of the Commission decision on Bt10 maize described below or the regulations relating to mycotoxins, heavy metals etc, the Directive does not specify analytical quality criteria for the methods to be used by laboratories providing certificates or official food control laboratories, although a group of experts at European level is working through a Scoop project to provide a validated method with known performance criteria. In the absence of specified detection limit and recovery values, laboratories could differ in their opinions on whether the dyes are present. As a result of these considerations, the Government Chemist is aware of the possibility of being involved in referee work relating to illegal dyes. GC is participating, therefore, in work at the European level and carrying out development work on detection methods.

Similarly, although official control laboratories are required to be accredited by the general provisions of Regulation 882/2004, there is no requirement for laboratories providing certificates for the purposes of this Directive to be accredited.

13 The Honey (Amendment) (England) Regulations 2005 ([2005 No. 1920](#))

This Statutory Instrument corrects two transposition errors and one spelling error in The Honey Regulations 2003, which implements Council Directive [2001/110/EC](#). The errors occurred during the transposition of Council Directive 2001/110/EC into UK law. The effect of the corrections will be to add 'pressed honey' to the list of honey products that may be described simply as 'honey' and to replace 'pressed honey' with 'bakers honey' in the list of those honey products that may not be described by certain additional quality criteria. The regulations have no effect on official laboratory or Government Chemist function.

14 The Tryptophan in Food (England) Regulations 2005 ([2005 No. 2630](#))

14.1 Purpose

These Regulations continue to prohibit the sale of food containing tryptophan, subject to some exceptions. The Regulations now allow the sale of food containing laevorotatory tryptophan (L-tryptophan) added to food supplements if certain conditions are met. The Regulations also make some changes to the exception regarding L-tryptophan added to certain foods for particular nutritional uses.

14.2 Background

Tryptophan is an amino acid, which is recognised as having calming properties and was used in food supplements until 1990. The Tryptophan in Food Regulations, prohibiting the use of tryptophan in food, were put in place in 1990 following the occurrence of eosinophilia-myalgia Syndrome (EMS) in people taking dietary supplements containing tryptophan in the US and UK. During the 1989 epidemic of EMS in the US, more than 1500 cases were reported and 37 deaths occurred. The Tryptophan in Food Regulations (1990) prohibit, in most cases, the addition of tryptophan to foods intended for human consumption. There are some exemptions for foods for particular nutritional purposes and for uses under supervision of healthcare professionals.

Between July 2003 and August 2004, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) reviewed current literature on tryptophan and EMS. A statement by COT was published on 4 August 2004, that on the balance of evidence, it is likely that L-tryptophan *per se* was not causal for EMS, and that EMS was due to one or more contaminants. However, there are uncertainties and it cannot entirely be ruled out that the apparent epidemic may have been due to the increased use of L-tryptophan supplements and the recognition of EMS. The statement concluded that laevorotatory tryptophan (L-tryptophan) as a dietary (food) supplement would not present an appreciable risk to health provided that it met the purity criteria specified in the European Pharmacopoeia (EP) and that the maximum recommended intake for an adult was 220 mg/day.

14.3 Effects

In light of COT's opinion, the Tryptophan in Food Regulations 1990 have been re-cast to:

- exempt L-tryptophan-containing food supplements from the prohibitions provided that they meet purity and recommended daily dose criteria;
- insert a qualification to the existing exemption in respect of L-tryptophan added to some foods for particular nutritional uses in that the added substance must comply with specific purity criteria laid down.

15 The Food Labelling (Amendment) (England) (No. 2) Regulations 2005 ([2005 No.2057](#)) and The Food Labelling (Amendment) (England) (No. 2) (Amendment) Regulations 2005 ([2005 No.2969](#))

15.1 Purpose

These Statutory Instruments amend the Food Labelling Regulations 1996 (SI 1996 No. 1499), as amended to implement Directive [2005/26/EC](#), which provides some exceptions from the allergen labelling requirements in food labelling Directive [2000/13/EC](#), as amended. SI 2969 has been made to implement Directive [2005/63/EC](#) which simply makes a correction to the list of exemptions so that fish gelatine used as a carrier for vitamin or carotenoid preparations and flavours is now exempt.

15.2 Background

Food allergy and food intolerance is thought to affect about 2 million people in the UK. Symptoms range from relatively mild to life-threatening (anaphylactic shock). Although most children grow out of it, there is no cure for food allergy or food intolerance, and the only way to avoid symptoms is to avoid the food in question.

New food labelling rules in England required food labels to be more comprehensive from 25 November 2005, so that consumers can identify those ingredients they may need or wish to avoid. The rules abolish the '25% rule', under which ingredients of a compound ingredient of a food do not have to be declared if the compound ingredient makes up less than 25% of the finished product, and introduce a requirement to declare any of 12 specified food allergens on the labelling.

According to these allergen labelling rules, any of 12 specified allergens and their derived ingredients must be labelled whenever they are present in pre-packed food, including alcoholic drinks. The purpose of Directive 2005/26/EC is to exempt from labelling the derivatives of food allergens that are not allergenic, provided there is sufficient scientific justification. This will reduce burdens on industry and improve information given to consumers.

16 The Food Labelling (Amendment) (England) Regulations 2005 (2005 No. 899)

16.1 Purpose

This SI provides for the implementation of Commission Directive [2004/77/EC](#), whose main provision is the requirement for confectionery and drinks containing certain levels glycyrrhizinic acid and its ammonium salt to be labelled with the indication 'contains liquorice' and for this to be coupled with a warning in certain cases. There are exemptions for food, which is not pre-packed, food which is pre-packed for direct sale, fancy confectionery products, small packages and certain indelibly marked glass bottles.

16.2 Background

There are estimated to be 170,000 deaths per year in England, where high blood pressure (hypertension) is a cause or contributing factor. High blood pressure affects around one in three people in England. People with high blood pressure are three

times more likely to develop heart disease and stroke and twice as likely to die from these diseases than those with normal levels.

Commission Directive 2004/77/EC and, therefore, the Regulations, address the risk that consumers suffering from hypertension may consume harmful amounts of glycyrrhizinic acid and/or its ammonium salts due to its presence not being declared on prepacked food.

Glycyrrhizinic acid occurs naturally in the liquorice plant *Glycyrrhiza glabra* while its ammonium salt is manufactured from aqueous extracts of the liquorice plant. Consumption above a certain level of glycyrrhizinic acid and its ammonium salt may give rise to, or exacerbate hypertension. The EU Scientific Committee on Food (SCF) concluded in 2003 that an upper limit for regular ingestion of 100mg/day of glycyrrhizinic acid and its ammonium salt provides a sufficient level of protection for the majority of the population. However the Committee noted that there are subgroups for which this upper limit might not offer sufficient protection, such as those with medical conditions related to disturbed water and electrolyte homeostasis.

The purpose of Directive 2004/77/EC is to ensure that consumers receive clear information about the presence of glycyrrhizinic acid or its ammonium salt in confectionery and beverages and that those with medical conditions related to disturbed water and electrolyte homeostasis are able to identify products they may need. In addition where products contain high levels of glycyrrhizinic acid or its ammonium salt consumers are informed that excessive intake should be avoided.

17 Charges for Inspections and Controls (Amendment) (No. 2) Regulations 2005 ([2005 No. 2715](#))

It is a requirement of Community law (Council Directive 96/23/EC) that Member States operate a National Surveillance Scheme (NSS) for residues of veterinary medicines and certain other substances in animals and animal products. It is also a Community requirement that charges are made in the sectors covered by the surveillance (red meat, poultry, eggs, milk, farmed fish and wild and farmed game) to recover the costs of operating the NSS. This SI increases the charges made in some sectors in the financial year.

The surveillance of animals and animal products for residues of veterinary medicinal products and certain other substances is a requirement under Community law. Council Directive [85/73/EEC](#) requires a charge to be made on the industries covered to fund the surveillance.

The surveillance scheme is implemented by the Veterinary Medicines Directorate in Great Britain under The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 ([SI 1729](#)).

Council Directive 85/73/EEC is implemented under The Charges for Inspections and Controls Regulations 1997 SI 2893. The primary enabling power to make charges is section 45 of the Food Safety Act 1990 (c.16).

The regulations have no effect on official laboratory or Government Chemist function.

18 The Veterinary Medicines Regulations 2005 ([2005 No.2745](#))

18.1 Purpose

The Regulations revoke and replace the controls and procedures concerning the authorisation, manufacture, supply and use of veterinary medicines. They include provisions on medicated feeds and feed additives and a revised fee structure.

These Regulations provide a single comprehensive set of controls on all aspects of veterinary medicines other than residues. They replace the provisions in the Medicines Act and approximately 45 statutory instruments that previously covered individual aspects of the production and placing on the market of veterinary medicines. Residues are not included because the European Commission is about to make proposals to revise the EU legislation. Changes required as a result will be incorporated into the Regulations when they are agreed so that there will be a single instrument. Industry has indicated their very strong support for this approach because The Medicines Act 1968 has proved cumbersome, and the procedures in the Act no longer fit the modern system for the control of medicines as set out in the new Directive [2004/28/EC](#).

The new regulations cover such aspects as manufacture, distribution, classification, administration to the animal, possession, post-authorisation surveillance and enforcement in relation to veterinary medicines. The Department decided that it would be very much easier for the user to have all this in one document rather than making the user refer to the Medicines Act for some aspects. Consequently the regulations disapply the Medicines Act, which has not been revoked as it continues to apply to some aspects of human medicines.

18.2 Background

Controls on veterinary medicines are necessary to ensure they are of consistently acceptable quality and are safe and effective when used in accordance with the manufacturers' directions. This includes the safety of consumers of produce from treated animals and of the environment. Since the coming into force of the Medicines Act 1968 UK legislation has regulated many aspects of veterinary medicines including their manufacture, distribution, supply and administration. However, the need for controls has to be balanced against the need for sufficient medicines to be available to ensure the health and welfare of animals. There is a need for new medicines to be developed in response to new and evolving disease patterns and it can take 10 years to develop a new medicine and bring it to the market. A well-established regime of controls exists based on the fundamental principle that veterinary medicines must be authorised before they may be placed on the market. Over the years these controls have been increasingly based in European legislation as authorisation and many related requirements have been harmonised across the EU. This has made it easier for companies producing the medicines to market their products across the Member States.

In 1995 two EU authorisation procedures were established. One is a centralised procedure, applicable to certain high technology and other innovative products, under which marketing authorisations are issued by the European Commission and are valid in all Member States. The other is a decentralised procedure under which the holder of a marketing authorisation issued in one Member State may apply to one or more other Member States to issue identical authorisations based on mutual recognition. In considering applications both procedures permit Member States to take account of differences such as local disease patterns, species, husbandry

techniques and environmental factors that may affect the safe and effective use of a product in a particular Member State.

18.3 Effects

[Schedule 5](#) of the Veterinary Medicines Regulations 2005 provides for controls over the manufacture, labeling, supply, placing on the market, possession, storage and transport of veterinary medicinal products. The definition of a veterinary medicinal product given in the regulations is

“(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or

(b) any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

This clearly includes animal feed that contains medicinal additives. Since the Medicines Act is disapplied to veterinary medicinal products, it appears that the specific reference in that Act to analysis by the Government Chemist does not apply to medicated feeds.

19 The Feeding Stuffs (England) Regulations 2005 ([2005 No. 3281](#))

19.1 Purpose

These Regulations consolidate the Feeding Stuffs Regulations 2000 and the various amendments to it. In addition, this instrument provides for the enforcement of [EC Regulation 1831/2003](#), which introduces new controls on the authorisation and use of feed additives in animal nutrition. It also transposes [Commission Directive 2004/116](#) which adds a new yeast-derived bioprotein product to the authorised list of such products.

Consolidation allows for the removal of superseded provisions relating to feed additives, now controlled by EC Regulation 1831/2003, which has replaced the previous control measure, Directive 70/524/EEC. The Feeding Stuffs (England) Regulations 2005 therefore provide for a range of offences and penalties for breaches of the relevant Articles of this EC Regulation.

19.2 Background

Feed additive (e.g. vitamin and trace elements) authorisations were subject to the provisions of [Directive 70/524/EEC](#), which was last substantially amended by [Directive 96/51/EC](#). One of the main principles was that only additives on an authorised list could be used in animal feed.

EC Regulation 1831/2003 strengthens the controls on the authorisation and use of feed additives. It retains the principle that only additives subject to an authorisation based on safety, quality and efficacy may be used in animal feed.

Previously, under [Directive 70/524/EEC](#), the competent authority of a Member State presented a dossier for consideration by the Commission and other Member States prior to authorisation. Under the new arrangements, new additives, and applications

for changes to the conditions of authorisation for existing additives, are assessed by the European Food Safety Authority (EFSA). Authorisations are renewable at ten-year intervals. Existing authorised additives, such as vitamins and trace elements, must be re-evaluated using updated criteria.

19.3 Effects

The Feeding Stuffs (England) Regulations 2005 implement harmonised EC measures on the marketing, labelling and composition of animal feedingstuffs. They include provisions intended to safeguard animal and human health, including maximum permitted levels for certain undesirable substances.

They provide, by reference to Commission Directive 2004/116 for the addition of a new yeast-derived product, *Candida guilliermondii*, to the Annex of Council Directive 82/471/EC, which lists in the annex the authorised bioproteins that may be used.

20 The Feed (Hygiene and Enforcement) (England) Regulations 2005 ([2005 No. 3280](#))

20.1 Purpose

This instrument introduces national enforcement powers in respect of EC Regulation 882/2004 on official feed and food controls and [EC Regulation No 183/2005](#), which lays down requirements for feed hygiene. It makes enforcement and other provisions in relation to animal feed law enforcement and it re-enacts other existing animal feed legislation.

20.2 Background

EC Regulation 882/2004 on Official Feed and Food Controls concerns the arrangements for the enforcement of feed and food rules and animal health and animal welfare law. The Regulation sets out the general approach that must be taken, and the principles that must be adopted, by the authorities in EU Member States that have responsibilities for monitoring and enforcing this legislation. In respect of animal feed, the Regulation replaces Council Directive 95/53/EC on official inspections in the field of animal nutrition.

EC Regulation 183/2005 (the Feed Hygiene Regulation) fulfils a commitment in the European Commission's White Paper on Food Safety of January 2000, aimed at strengthening feed safety, particularly in relation to operational standards of feed businesses and feed traceability. Its overall objective is to protect human and animal health from contaminated or otherwise unsafe food and feed. Following a number of feed contamination cases in continental Europe, the Commission wanted to strengthen standards throughout the feed chain and improve the rules so that, in case of a feed incident, feeds could easily be traced and recalled if appropriate.

The regulation replaces Council Directive 95/69/EC that provided for the approval and registration of feed businesses involved in the manufacture, use or marketing of certain feed additives. It extends these legislative requirements to most feed businesses, including farms (livestock farms storing and handling feed and arable farms selling crops for feed use), feed manufacturers not previously needing approval or registration, agricultural merchants, food businesses selling co-products for feed use, and importers of feed from third countries.

The Feed (Hygiene and Enforcement) (England) Regulations 2005 provide for the animal feed enforcement aspects of EC Regulation 882/2004 on official feed and

food controls and for the enforcement of EC Regulation 183/2005, by introducing relevant powers for competent authorities, attaching penalties and other administrative measures.

Some of the provisions that were contained in the Feeding Stuffs (Enforcement) Regulations 1999 have been re-enacted in The Feed (Hygiene and Enforcement) (England) Regulations 2005. Also, in order that the main provisions on animal feed law enforcement were contained in one set of regulations, the provisions on the enforcement of EC Regulation 178/2002 (previously set out in the Feeding Stuffs (Safety Requirements for Feed for Food-producing Animals) Regulations 2004), have been incorporated into the Feed (Hygiene and Enforcement) (England) Regulations 2005.

20.3 Effects

EC Regulation 183/2005 (the Feed Hygiene Regulation) requires most feed businesses (with just a few minor exceptions) to be approved and/or registered. Farms have to follow basic hygiene procedures in relation to the feed they use or grow and there is a code for feeding food-producing animals. The same regulation permits Member States to use existing official lists of farms (e.g. those held by agriculture departments) for the purposes of registration, which reduces the need for farmers to make applications for registration.

Other feed businesses must observe standards relating to facilities and equipment, storage and transport and record-keeping and apply the principles of HACCP (Hazard Analysis and Critical Control Points System). HACCP is a risk-based system, which provides a documented and structured approach to ensuring food/feed safety, and requires businesses to identify, manage and control hazards in their handling and production processes. To assist businesses to comply with the requirements, the Regulation envisages the adoption of Community codes of good practice.

Because one of the intentions of EC Regulation 882/2004 was to align the enforcement arrangements for food and feed law, the existing penalties for operating without approval or registration and failing to comply with conditions of approval/registration have been strengthened to bring them into line with those that apply to infringements of food law.

Part 4 of the Regulations mainly reflects existing legislative provisions and relates to local authorities' enforcement powers. However, the power to make feed business improvement notices and feed business prohibition orders is new and has been adapted from equivalent provisions in the Food Safety Act.

21 The Feeding Stuffs and the Feeding Stuffs ((Sampling and Analysis) (England) Regulations 2006 ([2006 No.113](#))

21.1 Purpose

This instrument transposes Commission Directives [2005/6/EC](#) and [2005/7/EC](#) on procedures for the sampling and analysis of undesirable substances (i.e. contaminants) in animal feed, and Commission Directive [2005/8/EC](#), which introduces new, and amends existing, permitted maximum levels for certain of these undesirable substances.

The Regulations also make consequential amendments to the Feeding Stuffs (Sampling and Analysis) Regulations 1999 (as amended) which implement earlier harmonised EC procedures for the sampling and analysis of animal feed, including the precise methods to be used in taking samples and conducting analyses, and the form of reporting on the results of such analyses. This is necessary to reflect the fact that the general obligation on Member States, formerly contained in Council Directive 95/53/EC, to ensure that sampling and analysis carried out in pursuit of official controls follows prescribed Community methods, is now given effect by Article 11 of Regulation (EC) No 882/2004.

Commission Directive 2005/6/EC inserts into the first of the Community's sampling and analysis Directives, 71/250/EEC, general provisions for reporting analytical results under the Undesirable Substances Directive, 2002/32/EC. Commission Directive 2005/7/EC amends Commission Directive 2002/70/EC by inserting into its annexes provisions relating to these procedures in the analysis of dioxins and dioxin-like PCBs in particular.

Commission Directive 2005/8/EC makes three amendments to existing maximum permissible limits (MPLs) for undesirable substances. Firstly, it extends the existing MPLs for mercury by adding an MPL for mercury in calcium carbonate (a mineral used in feed as a source of calcium and in which this toxic heavy metal occurs). Secondly, it amends the existing MPLs for fluorine in complementary feeds by replacing two existing entries with one relating the MPL to whether the phosphorus content, with which fluorine typically co-exists, is greater or lesser than 4% of the feed. Thirdly, the Directive amends the existing MPL for lead in green fodder by inserting a footnote to clarify what the term encompasses. UK domestic legislation currently uses the term "grass meal, lucerne meal or clover meal" instead of "green fodder", the term used in the Undesirable Substances Directive. The former term is more restrictive than that used in the Directive and so needs to be replaced.

21.2 Background

Requirements for laboratories, sample preparation, analytical procedures and the reporting of results for the analysis of both dioxins and dioxin-like PCBs were introduced by Commission Directive [2002/70/EC](#). The procedures for the analysis of these and other undesirable substances needed to be refined to introduce measurement uncertainty and correction for recovery.

All analytical results have a variability known as the measurement uncertainty, which, due to uncertainties inherent in the measurement procedures, has to be estimated to calculate the range within which the true value of the concentration of the analyte being determined will lie. Correction for recovery allows for the adjustment of analytical measurement to compensate for the likelihood that not all of the analyte will have been extracted from the sample prior to analysis.

Correction for recovery and an estimate of measurement uncertainty in the reporting of analytical results is, therefore, necessary. Commission Directive 2005/6/EC introduces general provisions relating to these procedures in the interpretation and reporting of analyses of undesirable substances in general, and Commission Directive 2005/7/EC introduces them to the analysis of dioxins and dioxin-like polychlorinated biphenyls (PCBs) in particular.

The maximum permitted levels (MPLs) for many undesirable substances were established some years ago. In accordance with more recent approaches to risk analysis, a review is being undertaken in the light of current scientific data on actual background levels by the relevant scientific panel of the European Food Safety Authority, which proposed the above changes.

21.3 Effects

The statutory instrument, by amendment of the Feedingstuffs (Sampling and Analysis) Regulations 1999, as amended, specifically requires that analysis for official control (including that carried out by the Government Chemist) must be carried out according to the general provisions of Article 11 of Regulation (EC) 882/2004. It also requires that in assessing compliance with legislative requirements, the analysed concentration must be corrected for recovery and the expanded measurement uncertainty subtracted from the analytical result.

For undesirable substances, the manner of reporting is also laid down in the Regulation. The result must be reported as $x \pm U$, where x is the analytical result and U is the expanded measurement uncertainty, using a coverage factor of 2 to give a level of confidence of approximately 95%. It must be stated whether or not the result has been corrected for recovery and the level of recovery must be indicated.

21.4 Comments on the legislation

In response to the consultation on this legislation, the Agricultural Industries Confederation, a feed industry trade association, suggested that there could be some additional costs associated with the introduction of measurement uncertainty and correction for recovery in the reporting of analyses of animal feed. However, this respondent was unable to quantify these potential costs.

A response from the Association of Public Analysts, suggested that the cost to laboratories for accreditation, validation of methods and calculation of measurement uncertainty could be significant, but did not provide specific figures to support its argument despite a subsequent request for quantification to help inform the Regulatory Impact Assessment. However, the Food Standards Agency is assessing the potential costs to analysts of accreditation under a separate measure on Official Feed and Food Controls, and the issue of any costs associated with the new procedures can be addressed as part of that exercise.

The Association of Public Analysts also requested that the implementation of Directive 2005/6/EC be deferred (to an unspecified future date), so that its requirements could be phased in alongside the accreditation and validation associated with another measure (EC Regulation 882/2004, which came into force on 1 January 2006). However, the Association has been advised that deferment is not a realistic option, as failure to meet the deadline for implementation could attract infraction proceedings from the European Commission.

The Association also stated that in its opinion a provision in the draft Regulations did not correctly replicate the intentions of Directive 2005/6/EC, in that it would apply measurement uncertainty and correction for recovery to the results of all analyses of feeding stuffs, irrespective of the analyte, rather than solely to analyses of undesirable substances. The relevant provision in the finalised Regulations has been amended to clarify that the footnote applies only to the analysis of undesirable substances.

Enforcement includes taking samples of feed and testing them for the presence of various components including undesirable substances, which is important for effective control of the feed chain and through that the ultimate health of the consumers of animal products. In general, analyses are undertaken by accredited agricultural analysts. Implementation of this regulation will provide clearer guidance for enforcement officers in cases where sampling has generated analytical results showing levels of apparent contamination very close to or just at the relevant MPL, by taking into account uncertainty and recovery when determining whether or not the

MPL has in fact been exceeded, thus formalising a measure which is already implemented in most enforcement laboratories.

It should be noted that none of the three Directives specify any new or revised levels of sampling and analysis for dioxins and dioxin-like PCBs. In consequence, Directives 2005/6/EC, 2005/7/EC and 2005/8/EC were expected to have little if any impact on enforcement authorities. Consequently, it is unlikely that numbers of samples of this type submitted for referee analysis will increase as a result.

22 The Feed (Corn Gluten Feed and Brewers Grains) (Emergency Control) (England) Regulations 2005 (2005 No. 1265)

22.1 Purpose

These Regulations implement the emergency control measures set out in [Commission Decision 2005/317/EC](#) to deal with the import from the US of two maize-derived animal feed materials which contain the unauthorised genetically modified organism Bt10.

22.2 Background

The Bt10 variety of GM maize has not been authorised for use anywhere in the world. However, the US authorities advised the European Commission in late March this year that, for the past four years, some exports of GM corn gluten containing Bt11 - which is authorised for import and use in food and feed in the EU - will have contained adventitious quantities of Bt10.

It subsequently transpired that the US authorities had known of this potential contamination since December 2004, when it had first been informed by Syngenta, the producer and owner of the Bt10 and Bt11 lines. Syngenta informed the European Commission that the Bt10 variety contains a gene conferring resistance to the antibiotic ampicillin. The US authorities stated that in view of the small quantities involved - approximately 800 tonnes of GM animal feed out of total maize exports to the EU per annum of 3.5 to 4.0 million tonnes - they did not consider there to be any food, feed or environmental safety issues associated with this contamination, although they did not address the antibiotic issue.

22.3 Effects

The Commission Decision requires Member States to permit corn gluten feed and brewers' grains originating in the US which either contain or are produced from genetically modified maize to be first placed on the market only where they are accompanied by an original analytical report by an accredited laboratory which demonstrates, based on a suitable and validated method, that the product does not contain Bt10. The testing costs incurred are to be borne by the feed business operators responsible for their first placing on the market.

22.4 Comments on the legislation

There could be additional costs to some traders importing the affected feed materials from the USA, as they will be responsible for providing an analytical report to demonstrate the absence from consignments of the Bt10 gene, and thus for the cost of the sampling and analytical work. There could also be additional costs to food

authorities, which are responsible for enforcement of the measure, but these will depend on the levels of sampling undertaken of material that is already in circulation.

The emergency measure recommends a method that should be used and provides links to the documented methods and validation data for a method developed by Syngenta, validated by Genescan and subsequently certified by the CRL as the EU official method for BT10 detection. However, these links do not appear to be active at the time of writing.

It is possible that referee analysis of corn gluten feed and brewers' grains could be required in cases of dispute, especially since it is not currently possible to establish a detection limit or other analytical quality criteria that should be applied in declaring absence of Bt10 from consignments.

Appendix I – Legislative changes in the food and agriculture sector April 2005 to March 2006

Title	Year	SI no.	Coming into force	Implementing EU Instrument	Number	Year
The Colours in Food (Amendment) (England) Regulations 2005	2005	519	1-Apr-05	Directive	47	2004
The Smoke Flavourings (England) Regulations 2005	2005	464	1-Apr-05	Directive	2065	2003
The Contaminants in Food (England) (Amendment) Regulations 2005	2005	775	11-Apr-05	Regulation	466	2001
				Directives	4,5,10	2005
The Miscellaneous Food Additives (Amendment) (England) Regulations 2005	2005	1099	19-Apr-05	Directives	114	2003
The Materials and Articles in Contact with Food (England) Regulations 2005	2005	898	29-Apr-05	Regulation	1935	2004
				Directive	14	2004
The Feed (Corn Gluten Feed and Brewers Grains) (Emergency Control) (England) Regulations 2005	2005	1265	30-Apr-05	Decision	317	2005
The Food (Chilli, Chilli Products, Curcuma and Palm Oil) (Emergency Control) (England) Regulations 2005	2005	1442	2-Jun-05	Decision		
The Honey (Amendment) (England) Regulations 2005	2005	1920	31-Aug-05	Directive	110	2001
The Food Safety (General Food Hygiene) (Amendment) (England) Regulations 2005	2005	2359	24-Sep-05			
The Veterinary Medicines Regulations 2005	2005	2745	30-Oct-05	Directive	28	2004
The Charges for Inspections and Controls (Amendment) (No. 2) Regulations 2005	2005	2715	31-Oct-05			
The Tryptophan in Food (England) Regulations 2005	2005	2630	11-Nov-05			
The Food Labelling (Amendment) (England) (No. 2) Regulations 2005	2005	2057	25-Nov-05	Directive	26	2005
The Food Labelling (Amendment) (England) (No. 2) (Amendment) Regulations 2005	2005	2969	24-Nov-05	Directive	63	2005
The Feeding Stuffs (England) Regulations 2005	2005	3281	1-Jan-06	Regulation	1831	2003
The Contaminants in Food (England) Regulations 2005	2005	3251	1-Jan-06			
The Food Hygiene (England) Regulations 2005	2005	2059	1-Jan-06	Regulation	882	2004

Appendix I (Continued)

Title	Year	SI no.	Coming into force	Implementing EU Instrument	Number	Year
The Official Feed and Food Controls (England) Regulations 2005	2005	2626	1-Jan-06	Regulation	882	2004
The Feeding Stuffs (Application to Zootechnical Additives etc.) (Scotland) Regulations 2005	2005	3362	3-Jan-06	Regulation	882	2004
The Food Hygiene (England) Regulations 2006	2006	14	11-Jan-06	Regulation	882	2004
The Official Feed and Food Controls (England) Regulations 2006	2006	15	11-Jan-06	Regulation	882	2004
The Feeding Stuffs and the Feeding Stuffs (Sampling and Analysis) (Amendment) (England) Regulations 2006	2006	113	16-Feb-06	Directives	6,7,8	2005
The Food Labelling (Amendment) (England) Regulations 2005	2005	899	20-May-06	Directive	77	2004
The Feed (Hygiene and Enforcement) (England) Regulations 2005	2005	3280	1-Jan-06	Regulation Regulation	882 183	2004 2005