Consumer Law Bulletin

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Filing instructions: This Bulletin contains material available on 1 December 2012. It should be filed behind the Bulletins Guide Card and in front of Bulletin No 314. **Remove Bulletin 302**. If desired Bulletin 302 may be retained outside the Binder for future reference. The Binder should now contain Bulletins Nos 303 to 315.

FAIR TRADING

Use of Civil Sanctions and Powers in the Regulatory Enforcement and Sanctions Act 2008

Written Ministerial Statement – Rt Hon Michael Fallon, Minister of State for Business and Enterprise; Department for Business, Innovation and Skills – 8 November 2012:

"I am announcing today that when considering whether to make Orders under the Regulatory Enforcement and Sanctions Act 2008 to provide a regulator with powers to impose certain civil sanctions as an alternative to prosecution the Government will, in general, observe the following principles:

- Powers to impose Fixed Monetary Penalties, Variable Monetary Penalties and Restoration Notices will, as a general rule, only be granted where their use is restricted to undertakings with more than 250 employees; and
- Powers to impose Enforcement Undertakings, Stop Notices and Compliance Notices may be granted without restriction as to the size of undertaking against whom they might be used.

I believe that this approach should enable Departments to introduce Orders under the Act that provide for a more flexible enforcement system and reduce the burdens on criminal courts. Safeguards on the use of civil sanctions are already contained in the Act.

This policy will provide a further safeguard as regards new Orders under the Act namely that, as a general rule, Fixed Monetary Penalties, Variable

Monetary Penalties and Restoration Notices will only be applied to larger companies rather than to Small and Medium Enterprises who might feel less equipped to challenge the basis for such sanctions.

Any future plans by Departments to introduce these Orders will be announced by them in line with usual practice."

***Civil Enforcement Remedies – Extending Remedies for Public Enforcers of Consumer Law* (*URN 12/1193*)**

Consultation seeking views on proposals to make a flexible range of remedies available to enforcers, and possibly the courts. These remedies aim to increase business compliance with the law, improve redress for consumers affected by the breach, and empower consumers to exercise greater consumer choice. Responses by 31 December 2012. (See URN 12/1194 for the related impact assessment.).

FOOD

NEW EU LEGISLATION

Registration as PDO: "Isle of Man Queenies" – Regulation 1030/2012 – (OJ No L 308; 8.11.2012)

This registration enters the name in the register of protected designations of origin and protected geographical indications: "Isle of Man Queenies (PDO)". It appears in Class 1.7: "Fresh Fish, molluscs and crustaceans and products derived therefrom."

***Nutrition Claims – Regulation 1047/2012* (*OJ No L 310; 9.11.2012*)**

This Regulation amends the Annex to Regulation 1924/2006. It addresses the use of the claim: "NO ADDED SODIUM/SALT". Also, in the entry concerning "REDUCED [NAME OF THE NUTRIENT]" new provisions are added addressing the claims "*reduced saturated fat*" and "*reduced sugars"*. Products placed on the market prior to 1 June 2014 which do not comply with the requirements of Regulation 1924/2006, as amended by this Regulation, may be marketed until the stocks are exhausted. This Regulation entered into force on 29 October 2012.

***Authorisation of Health Claim – Regulation 1048/2012* (*OJ No L 310; 9.11.2012*)**

This Regulation, from 29 October 2012, authorises the health claim made on foods and referring to the reduction of disease risk: "Barley beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease." Conditions of Use: "Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3g of barley beta glucan. The claim can be used for foods which provide at least 1g of barley beta glucan per quantified portion."

Changes re: Polyglycitol Syrup – Regulation 1049/2012 (OJ No L 310; 9.11.2012)

This Regulation amended Annex II to Regulation 1333/2008 from 29 November 2012 as regards the use of polyglycitol syrup in several food categories.

Specification Changes re: Polyglycitol Syrup – Regulation 1050/2012 (OJ No L 310; 9.11.2012)

This Regulation amended Regulation 231/2012 from 29 October 2012 as regards the use of polyglycitol syrup in several food categories.

FEEDINGSTUFFS

NEW EU LEGISLATION

Endo-1,4-beta-xylanase as Feed Additive – Regulation 989/2012 (OJ No L 297; 26.10.2012)

This Regulation concerns the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MULC 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MULC 49754) as a feed additive for laying hens and minor poultry species for fattening and laying (holder of authorisation Aveve NV). It entered into force on 15 November 2012.

Propionibacterium acidipropionici (CNCM MA 26/4U) as Feed Additive – Regulation 990/2012 (OJ No L 297; 26.10.2012)

This Regulation concerns the authorisation of a preparation of *Propionibacterium acidipropionici* (CNCM MA 26/4U) as a feed additive for all animal species. The preparation belongs to the additive category "technological additives" and to the functional group "silage additives" and is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex. It entered into force on 15 November 2012.

Authorisation of Zinc Chloride Hydroxide Monohydrate as Feed Additive – Regulation 991/2012 (OJ No L 297; 26.10.2012)

This Regulation concerns the authorisation of zinc chloride hydroxide monohydrate as a feed additive for all animal species. The preparation belongs to the additive category "nutritional additives" and to the functional group "compounds of trace elements" and is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex. It entered into force on 15 November 2012.

Micro-Organisms in Complete Feedingstuffs – Regulation 1018/2012 (OJ L 307; 7.11.2012

This Regulation amends Regulations 232/2009, 188/2007, 186/2007, 209/2008, 1447/2006, 316/2003, 1811/2005, 1288/2004, 2148/2004, 1137/2007, 1293/2008, 226/2007, 1444/2006, 1876/2006, 1847/2003, 2036/2005, 492/2006,

1200/2005, and 1520/2007 regarding the maximum content of certain micro-organisms in complete feedingstuffs. It entered into force on 27 November 2012.

Endo-1,4-beta-xylanase as Feed Additive – Regulation 1019/2012 (OJ No L 307; 7.11.2012)

This Regulation amends Regulation 1096/2009 regarding the minimum content of endo-1,4- beta-xylanase produced by *Aspergillus niger* (CBS 109.713) as a feed additive in feed for chickens for fattening and for ducks (holder of authorisation BASF SE). It entered into force on 27 November 2012.

Endo-1,4-beta-xylanase as Feed Additive – Regulation 1021/2012 (OJ No L 307; 7.11.2012)

This Regulation concerns the authorisation of endo-1,4- beta-xylanase produced by *Trichoderma reesei* (ATTC PTA 5588) as a feed additive for minor poultry species other than ducks (holder of authorisation Danisco Animal Nutrition. It entered into force on 27 November 2012.

MEDICINES

NEW LEGISLATION

Health Service Branded Medicines (Control of Prices and Supply of Information) Amendment Regulations 2012/2791 – in force 1 January 2013

These regulations were made under the National Health Service Act 2006 and apply to the United Kingdom amending reg 2 of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008, SI 2008/3258. That regulation specifies the maximum price which may be charged for the presentation of a branded medicine supplied for health service purposes, unless the medicine falls within a voluntary scheme for limiting prices or profits or the price is determined under other provisions of the Regulations. The amendment provides that the maximum price of a presentation is calculated by deducting 5.3% (instead of 5.5%) from the price for which that presentation was on sale for health service purposes in England on 1 December 2008. The amendment mirrors a change to the Pharmaceutical Price Regulation Scheme 2009, which has effect on 1 January 2013.

INFORMATION

Merger of MHRA/NIBSC

On 1 April 2013 the National Institute for Biological Standards and Control (NIBSC), currently part of the Health Protection Agency (HPA), will officially become a new 'centre' of the Medicines and Healthcare products Regulatory Agency (MHRA) alongside the Clinical Practice Research Datalink (CPRD). MHRA and NIBSC already work closely together and have common interests in managing risks associated with biological medicines,

facilitating development of new medicines safely and effectively, and maintaining UK expertise and ability to contribute to assuring the quality and safety of medicines in Europe and beyond. The developments will create a new organisation that is a world leader in supporting science and research and the regulation of medicines and medical devices, and will strengthen the support provided to the UK's medicine's industry.

Black Cohosh and Liver Failure

Following previous warnings relating to the use of "Black Cohosh" the Medicines and Healthcare products Regulatory Agency has issued a further reminder highlighting the risk of liver problems arising from the use of the herbal remedy Black Cohosh. A product commonly used to relieve menopausal symptoms, this latest reminder follows a serious case of liver failure. After using a herbal product containing Black Cohosh the consumer suffered liver failure, requiring a transplant. The investigation of this case and of the product involved is ongoing. To date MHRA has received through its medicines safety monitoring reporting system – the Yellow Card Scheme – some 53 reports of adverse reactions suspected to be associated with the use of Black Cohosh. The majority of the reports (36) have involved liver problems including abnormal liver function, jaundice and hepatitis. Black Cohosh products are available for general sale in pharmacies, supermarkets and health food shops. Currently, there are both authorised (registered under the Traditional Herbal Registration (THR) scheme) and unlicensed products legally on the market. Since 2006 the MHRA has asked all manufacturers of Black Cohosh products to ensure that an appropriate warning about possible liver problems is included on the label. The MHRA recently became aware that some unlicensed products containing Black Cohosh may not have this warning and have issued a reminder to the sector on the need for products to carry appropriate warnings on their products' labels. MHRA always recommends that registered herbal products are used. Registered products can be identified by the Traditional Herbal Registration (THR) number or logo on their packaging. These products have been assessed and quality checked to ensure that they are acceptably safe to use and are accompanied by a leaflet with information on how to use them with any possible side effects listed. Unlicensed products do not have the THR registration or logo number and have not been assessed for quality. Users should always consult a pharmacist or doctor to make sure that an herbal remedy is suitable for them to take and won't interact with other medicines they may be taking.

Comment: Against the background of repeated advice and warnings issued by MHRA an unsuspecting consumer injured by a product inadequately labelled would create a civil cause of action under the "no fault" provisions of "product liability".

Pseudoephedrine/Ephedrine-containing Medicines – 2012 Review of Misuse

In 2008, legal measures were introduced in the UK to manage the risk of misuse of cold and flu medicines containing pseudoephedrine and ephedrine

in the illegal manufacture of methylamphetamine (crystal meth). The measures included reduced pack sizes, and a tighter control on sales. These measures have been reviewed yearly since 2008 (see MHRA Public Assessment Reports from 2009, 2010 and 2011), and were reviewed again in 2012. As with previous reviews, the 2012 review concluded that the measures are continuing effectively to manage the risk of misuse of medicines that contain pseudoephedrine or ephedrine. A Public Assessment Report which summarises the findings from the 2012 review is now available on the MHRA website.

Clinics Advertising Botulinum Toxin Products – September 2012

The following companies have amended their advertising following MHRA action on complaints to ensure that prescription only medicines are not promoted to the public:

- Absolutely Flabuless, Tamworth, Staffordshire.
- Ash Labib, Wolverhampton, West Midlands.
- Beauty By Faye Dove, Mansfield, Nottinghamshire.
- Cannock Chiropodist/Dermapod, Staffordshire.
- Discreet Beauty, Cheshire.
- Fiona Clossick Aesthetics, Birmingham [Aug 12/87].
- Just Beauty Laser Clinic, Coventry.
- Natural Face Lift Company, Birmingham.
- Skin Radiance, Herald Way, Castle Donington.

Please note that the listing relates to specific advertising action taken on a particular date and provides no endorsement of the ongoing practices of the clinic.

MHRA – Views Sought on Regulation of Medical Devices

The Medicines and Healthcare products Regulatory Agency is seeking the views of healthcare professionals and the public on draft European laws for the regulation of medical devices such as breast and hip implants and hospital equipment, such as dialysis machines. Medical device regulation continues to be the subject of heated debate following PIP breast implants issues and recent safety concerns involving metal-on-metal hips. MHRA has been pressing the European Commission for four years now to strengthen the current system of regulation. MHRA now launch a ten-week consultation enabling healthcare professionals and the public to give their views on whether new draft legislation from the European Commission goes far enough in the following areas:

- Promoting the safety of medical devices and ensuring public confidence in the regulatory system.

- Improving the organisations (notified bodies) which assess the safety of medical devices.
- Ensuring transparency and ensure better collaboration between national regulators.

The consultation started on Monday 12 November for a ten-week period, ending 21 January 2013. A consultation page can be found on MHRA website.

ALERT

Medical Device Alert

Batteries for HeartStart XL defibrillator/monitor manufactured by Philips and distributed by Philips and Cardiac Services UK & Ireland (MDA/2012/077).

Details: Batteries for HeartStart XL defibrillator/monitor. Battery part number M3516A. Batch labelled "Made in Taiwan" with "Date of Manufacture" code "R-2011–12". Manufactured by Philips and distributed by Philips and Cardiac Services UK & Ireland. There is risk of immediate and unexpected loss of critical monitoring, defibrillation or non-invasive pacing. If a HeartStart XL defibrillator/monitor is not connected to the mains and is used with a battery from the affected batch, it may shut down unexpectedly without providing the user with a low battery warning or audible alarm. The manufacturer published a Field Safety Notice in September 2012 to notify users and prompt them to take action. The manufacturer has not received sufficient confirmation that this FSN had been received and acted upon. Action by all those responsible for the use or maintenance of the devices:

- Identify HeartStart XL defibrillator/monitors with affected batteries and affected spare batteries.
- If you have affected batteries, follow the guidance given in the Field Safety Notice. In particular:
  - do not use device on battery power alone; and
  - ensure you have access to an appropriate alternative device;
  - contact the manufacturer to arrange for a replacement battery:

Philips Healthcare, Philips Centre, Guildford; GU2 8XH. Tel: 0870 532 9741

SAFETY

INFORMATION

Guidance on the Pyrotechnic Articles (Safety) Regulations 2010

This publication provides informal guidance on the regulations applying to fireworks and other pyrotechnic articles. It is intended to assist people to comply with the regulations, covering age limits on supply of fireworks and

pyrotechnic articles, the new requirements concerning "persons with specialist knowledge", and how the transitional provisions work. See BIS website – URN: 12/1244

Electromagnetic Compatibility Regulations 2006 – Guidelines on Appointment of Notified Bodies

This publication describes the UK requirements for assessing and appointing notified bodies under the Electromagnetic Compatibility Regulations 2006/3418, which implement the provisions of the EC Electromagnetic Compatibility Directive 2004/108 into UK law. See BIS website – URN: 12/1249

TRADE DESCRIPTIONS

Civil Enforcement Remedies Consultation

This consultation sets out proposals to extend the range of remedies available to enforcers of consumer law. The proposals would allow remedies aimed at achieving one or more of three outcomes:

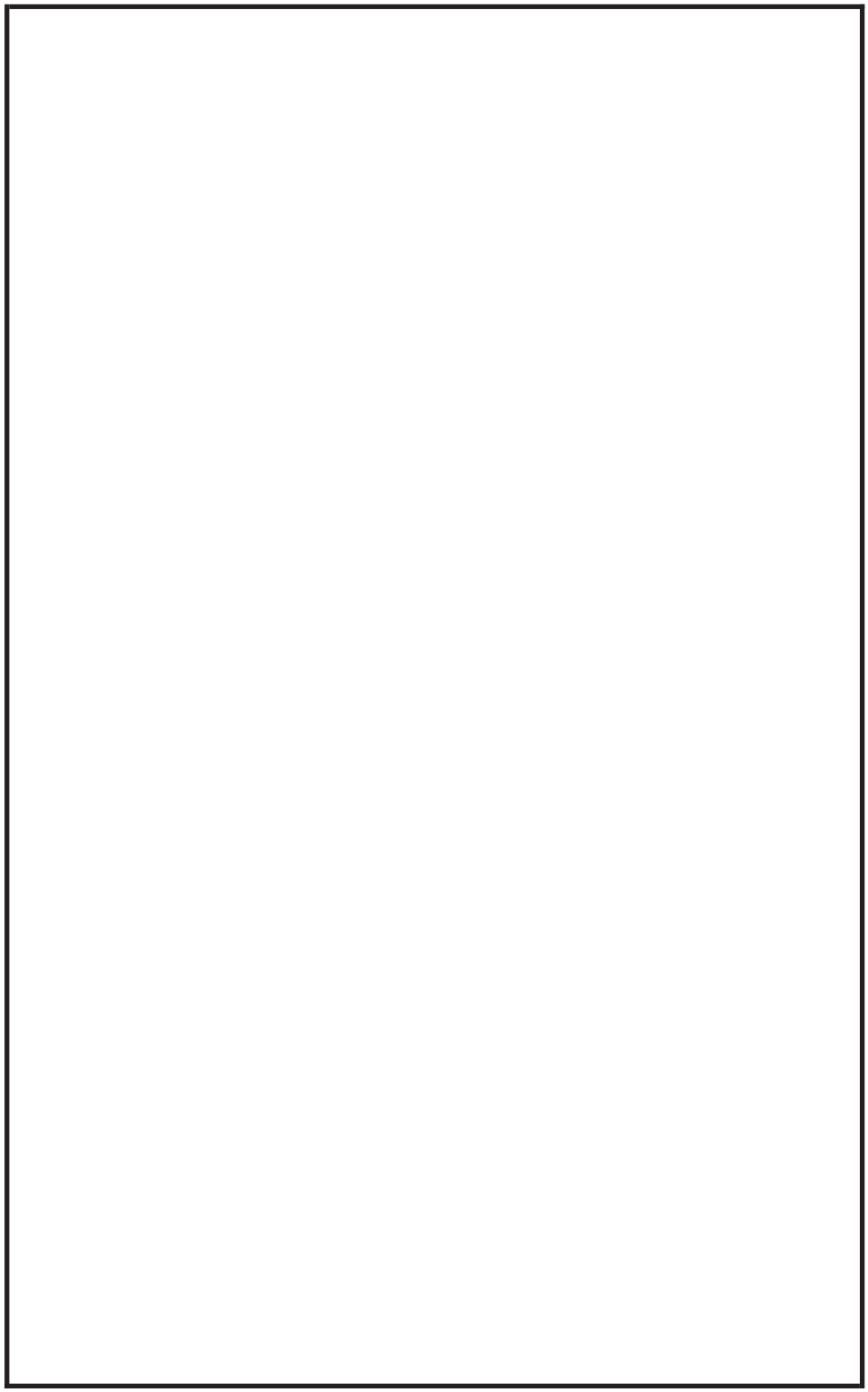
- increased business compliance with the law;
- improved redress for consumers affected by the breach; and
- more confident consumers who are empowered to exercise greater consumer choice.

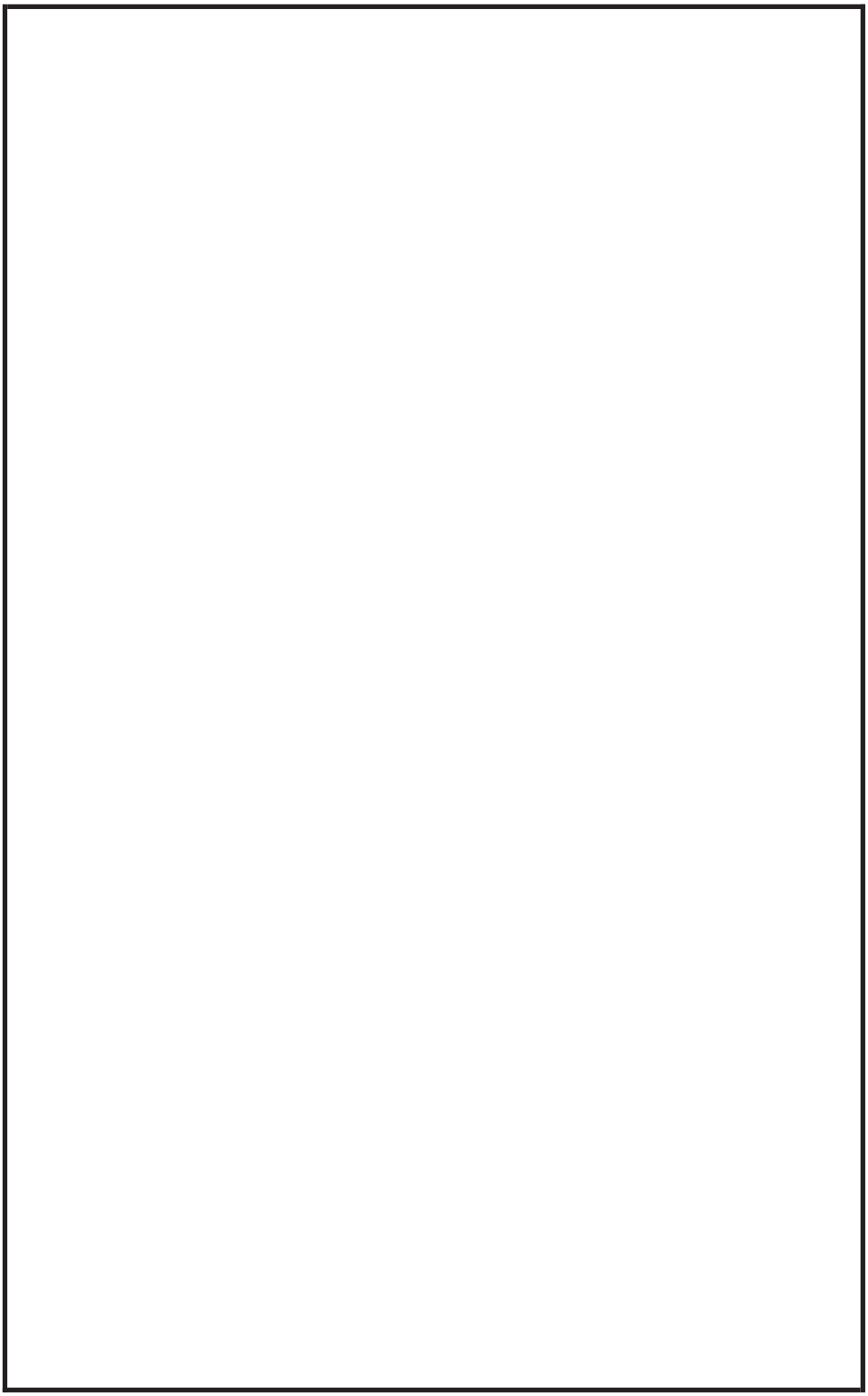
The consultation considers whether implementation of the Regulatory Enforcement and Sanctions Act 2008 or introducing new remedies under Pt 8 of the Enterprise Act 2002 would be most appropriate. Part 8 currently allows for court-based Enforcement Orders which can be used to stop a business behaving in a particular way. These proposals form part of a proposed wider reform of consumer law intended to simplify and clarify it to reduce business compliance costs and empower consumers. Implementation of the proposals would require primary legislation, the proposal for which is through a "Consumer Bill of Rights". Details appear on the BIS website; closing date for responses 31 December 2012.

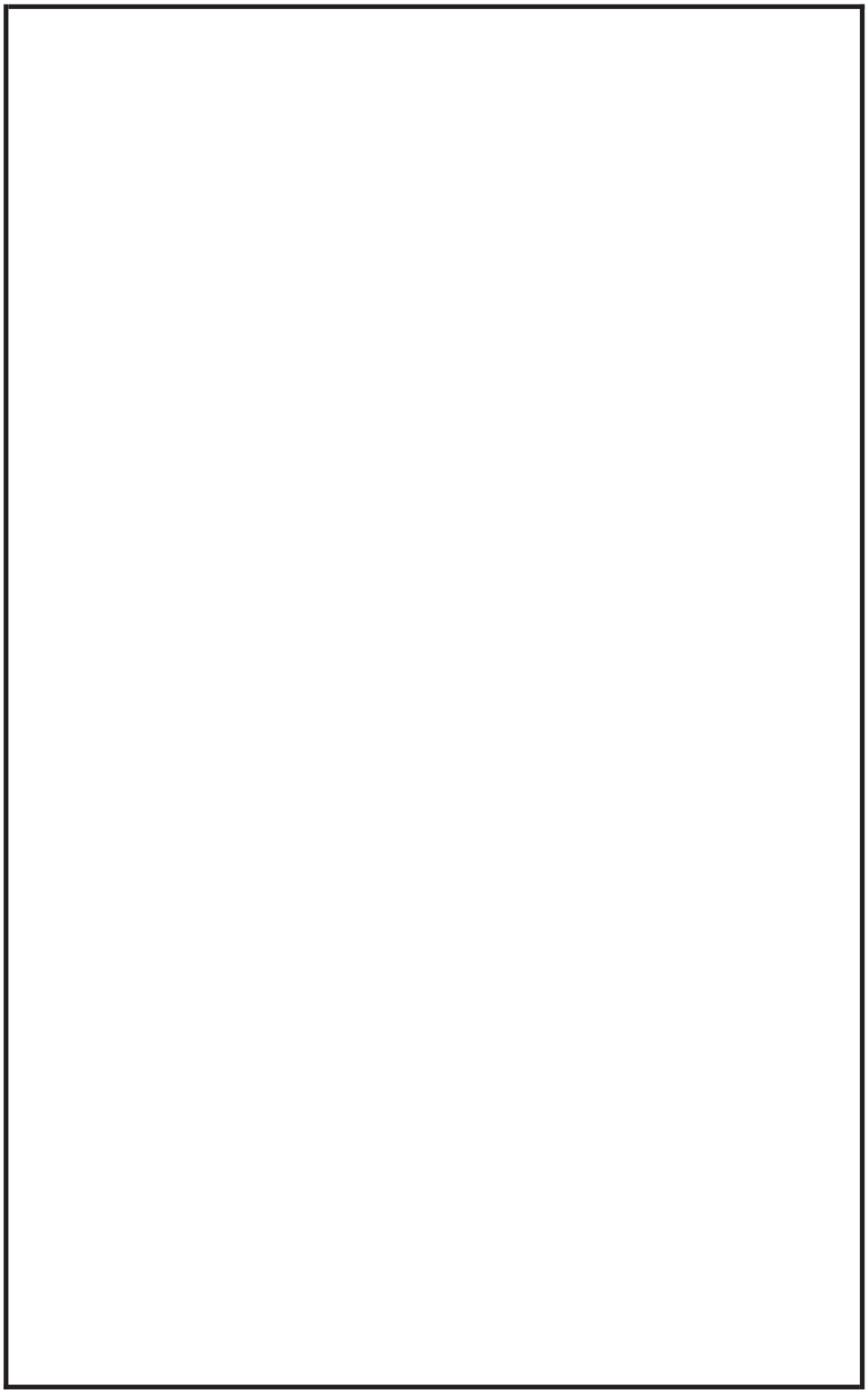
WEIGHTS & MEASURES

Revision of OIML R61 Gravimetric Filling Instruments

The National Measurement Office is seeking the views of all UK stakeholders in relation to a proposed revision to the technical working document for gravimetric filling instruments. OIML working groups aim to harmonise working standards for International Legal Metrology. This consultation is a review of OIML R61 Gravimetric Filling Instruments. Relevant documents and a template form for comments are available on the NMO website. Deadline for comments: 30 March 2013. Contact: Morayo Awosola, National Measurement Office, Tel: +44 0208 943 7287. Email: Morayo.awosola@nmo.gov.uk.







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Published by LexisNexis

Printed in Great Britain by Hobbs the Printers Ltd, Totton, Hampshire

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www.fsc.org
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Paper from responsible sources
FSC® C020438

ISBN 978-1-4057-7242-6

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