



European Internal Market

**Proposals for a Regulation on
Accreditation and Market
Surveillance and a Decision on
a Common Framework for the
Marketing of Products**

[COM(2007)37 Final & COM(2007)53 Final]

A Consultation Document

March 2007

URN 07/771

This consultation seeks your views on a new Internal Market package of complementary measures (Proposals for a Regulation and a Decision) that have been designed to strengthen and modernise the conditions for the marketing of a wide range of products in the EU.

Many products are already subject to Community harmonisation legislation, but the new proposals have been designed to strengthen the framework within which products are manufactured and traded, building upon the well established existing mechanisms (under the 'New Approach') to ensure that safe products can circulate freely. This mechanism is widely regarded as a business-friendly approach to regulation because it relies on the use of mandated standards whilst giving businesses flexibility in compliance and does not hinder innovation.

New Approach Directives played an important role in the completion of the Internal Market in goods in 1992 and currently help to regulate some 20% of products traded throughout the EU, worth approximately 1.5 trillion Euros annually. Products regulated under this legislation include electro-technical products, machinery, radio and telecommunications terminal equipment, toys, medical devices, construction products and others.

The Proposal for a Regulation will reinforce Market Surveillance structures to protect citizens from unsafe products (including those coming from outside of the EU) and levelling the playing field for compliant businesses, by removing those products from the market and taking action against fraudulent manufacture. The Regulation is also designed to enhance confidence in the conformity assessment of products by strengthening the role of Accreditation for testing, certification and inspection bodies.

The Proposal for a Decision contains a toolbox of additional measures which will be integrated into the future legal framework as either new sector specific directives are brought forward or existing sectoral directives are revised or updated. This will clarify commonly used procedures and terms (which are often used differently) so that all stakeholders can be clear on relative responsibilities. In addition there are new rules to enhance confidence and trust in CE marking which will help to increase transparency and strengthen the system.

You should also be aware of the separate consultation on the Proposal for a Regulation of the European Parliament and of the Council on the application of certain national technical rules to products lawfully marketed in another Member State. This can be found at: <http://www.dti.gov.uk/consultations/page38029.html>.

Starting date: 9 March 2007

Closing date: 1 June 2007

Enquiries to: Ana Nicola
Sustainable Development & Regulation Directorate
Office of Science and Innovation
Department of Trade & Industry
151 Buckingham Palace Road
London SW1W 9SS

Tel: 020 7215 1573

Fax: 020 7215 1340

E-mail: <mailto:new.approach@dti.gsi.gov.uk>

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1. Executive Summary

This consultation document seeks your views on these proposals, which were adopted by the European Commission on 13 February 2007 and are currently under consideration by the European Parliament and the Council of Ministers.

The Consultation features two separate proposals that need to be considered in parallel. The first is a *Regulation* on Accreditation and Market Surveillance which when adopted will have direct effect in Member States; the second is a *Decision* that covers conformity assessment procedures, the notification of conformity assessment bodies and CE marking. When adopted it will not have direct effect in Member States, but will set a formal framework for all new European legislative proposals in this area. The proposals, together, aim to improve the free movement of goods within the EU by streamlining existing mechanisms for the circulation of safe goods and meet Better Regulation principles by facilitating a risk-based approach.

The purpose of this consultation is to obtain views and information on the likely effects of the Commission's Proposals on UK Businesses, citizens, consumers and public authorities, to better inform the UK Government's position in the negotiations in the Council and elsewhere. This consultation will run from 9 March 2007 to 1 June 2007. Early responses would be appreciated.

More detailed explanations of the New Approach and its review can be found at:

<http://www.dti.gov.uk/innovation/strd>
http://ec.europa.eu/enterprise/newapproach/review_en.htm

The European Commission has conducted a Community-wide consultation, May-August 2006, and the results of this can be seen on the Europa website at:

http://ec.europa.eu/enterprise/newapproach/pdf/naga_ipm_consultation_results.pdf

THE REGULATION PROPOSAL

Accreditation

The Commission Proposal for a Regulation will create a European legal framework for Accreditation (for an explanation, refer to the Glossary). The framework aims to improve the functioning of the Internal Market by ensuring that the market has confidence that conformity assessment bodies (i.e. testing, certification and inspection bodies), themselves operate to acceptable standards.

The Proposal will lay down the scope of Accreditation, the general principles for Accreditation, requirements on its operation, cross-frontier Accreditation, requirements for national accreditation bodies, monitoring national accreditation bodies' compliance with requirements, requirements for peer evaluation of such accreditation bodies and certain other matters.

Market Surveillance

The Commission Proposal for a Regulation will create a Community Market Surveillance (for an explanation, refer to the Glossary) Framework for, and controls of, products entering the Community Market within a broad scope (defined in Article 13) covering all products subject to Community harmonisation legislation (with a few exclusions).

The obligations are placed on Member States to organise market surveillance, to take appropriate market surveillance measures to ensure compliance with the legislation, to exchange information on measures taken, and to co-operate with each other and with the European Commission. The Commission is required to organise an appropriate information support system and to coordinate market surveillance initiatives in which the Member States must ensure appropriate participation by their market surveillance authorities. There are also requirements for Controls of Products entering the Community Market: these are successor provisions to an existing Community Regulation – 339/93/EEC (which will be repealed) but would introduce important new features. The draft Regulation requires members to lay down penalties that must be effective, proportionate and dissuasive.

Definitions

The draft Regulation and the Decision both contain definitions of the key terms used. These are discussed in more detail below.

Other provisions

There are new provisions on Community Financing in the areas of Accreditation and Market Surveillance and associated budgetary provisions. Also, a duty is placed on the Commission to draw up technical guidelines to facilitate the implementation of the Regulation.

THE DECISION PROPOSAL

A notable feature of the proposal to use a Decision in respect of the overall proposals, is that the Decision, when adopted, will not have immediate legal consequences in Member States. It will be directed towards the institutions of the European Union. It is designed to constrain departure from its provisions when new legislation in this area is proposed, so that when new proposals for product legislation come forward (whether they are new or are being revised or for amendment) the Commission, Council and Parliament will be obliged to cast the law using the decision provisions as the framework. The Commission envisages that any sectoral Proposals adopted from now onwards will be drafted on this basis so that such negotiations would only concentrate on matters that are unique to a piece of legislation e.g. defining its scope, drafting appropriate essential requirements and choosing appropriate conformity assessment procedures on the basis of expert risk assessment. It will, however, remain open in a particular piece of sectoral legislation to depart from the Decision's framework but a very good case will need to be made for doing so in every instance. The Decision is thus intended to be a robust future model for harmonisation of all European Product legislation in respect of the relevant features that it covers.

The principal features of the Decision

“Title I”

General principles for the drawing up of Community legislation laying down the conditions for the marketing of products

In these provisions, the Decision defines the scope of the measure – Community legislation harmonising the conditions for the marketing of products and lists certain specific exclusions. It defines the process of protecting the public interest: legislation shall restrict itself to setting out essential requirements except where this is not possible or appropriate. It provides for the use of harmonised standards. It lays down provisions on conformity assessment procedures and states that where they are to be used in legislation they must be chosen from those listed in Annex I to the Decision (this Annex constitutes the major part of the text of the Decision). It specifies the form an EC Declaration of Conformity is to take in those pieces of legislation that provide for it (see Annex 2).

“Title II”

Reference provisions for Community legislation laying down the conditions for the marketing of products

Chapter 1 - Definitions

Matching the Regulation Proposal, there is a list of key definitions including “making available on the market” “manufacturer” and other economic operators.

Chapter 2 – Obligations of Economic Operators

There is a very important attempt to define rational sets of obligations for every key player in the supply chain – “manufacturers”, “authorised representatives”, importers” and “distributors”. There are also important provisions on the traceability of goods.

Chapter 3 – Conformity of the Product

Products which are in conformity with harmonised standards that have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the relevant requirements of the EU legislation. There are provisions on the role of the EC Declaration of Conformity and the responsibilities associated with it. There are provisions on CE Marking and on Member States’ duty to ensure its proper use. It should be noted that it is mainly “New Approach” legislation, at present, that makes provision for CE marking.

Chapter 4 – Notification of Conformity Assessment bodies

There are provisions on the duty of Member States to notify the Commission of bodies authorised to carry out third-party conformity assessment tasks and the requirements relating to

notifying authorities and the notification procedure. There are requirements for the notified bodies themselves that include provisions on sub-contracting and on information exchange and co-ordination between notified bodies. There are also requirements for accredited in-house bodies that supply conformity assessment services exclusively to the undertaking of which it forms a part but which are not notified to the Commission.

Chapter 5 – Safeguards Procedures

There are procedures to deal with products that present a risk – procedures for action at both national and Community level.

The UK's current view of the proposals is broadly as follows:

The Regulation Proposal

We should like to consolidate the process of Government-recognised **Accreditation** and make it universal throughout the EU by establishing a European legal framework for Accreditation, which we believe would provide a boost to the whole system of third party certification and to the cost competitiveness of British and European business in the process. This is our priority topic in the whole New Approach agenda and we are very supportive of these features of the Commission's Proposals. We believe they take forward the Better Regulation and Business Competitiveness agendas in a way that closely reflect our objectives in this area of policy-making.

Regarding **Market Surveillance**, our perception - based largely on the existing New Approach legislation - is that much of what is proposed only spells out or recasts what we consider is already required of the public services and should be undertaken to make a reality of the Internal Market. However, there are important proposals on **Border Controls** that will need to be evaluated closely because they appear to place a substantial new obligation on customs authorities.

There is a widespread perception across the EU that levels of surveillance and enforcement are uneven and inadequate to the detriment of fair competition, user safety and the notion of the Internal Market. We should, however, welcome the insights of other parts of the public services and indeed of Business, Consumer and other stakeholders – particularly those from non-New Approach areas – Old Approach, environmental legislation and any other harmonising product legislation. Should the exclusions be extended? Should the exclusions be more restricted?

Our main problem is that while a Council of Minister's Resolution of November 2003 invited the Commission to bring forward measures to enhance the implementation of the New Approach legislation, the Commission has at its own initiative decided to bring forward provisions for the harmonization of all Community Product harmonising legislation. The Commission's impact assessment explains its reasons – arguing that the key issues are common across the New Approach, Old Approach and other legislative areas. It does this, however, without actually defining what it is referring to – it argues that this is an impossibly large task. We do not regard that as a satisfactory response – particularly in relation to Market Surveillance because that area

of responsibility is in the Regulation Proposal and would take effect across the board from a set date in contrast to the areas of responsibility that are included in the Decision Proposal. If we are to screen our national transposing legislation for compliance with the Market Surveillance provisions of the Regulation, we need to know the exact scope – or else we could end up with 27 Member States interpreting it differently. We have been calling for the Commission to do this since its refusal to define the scope of these provisions became clear in autumn 2006. We shall continue to press for this.

The Decision Proposal

From a New Approach standpoint the key features look largely satisfactory. We do have some more specific concerns as already expressed in our reports to stakeholders on the informal discussions in the advisory Senior Officials Group on Standardization and Conformity Assessment (SOGS) that acted as the informal Commission Working Group in the development of these proposals (we have regularly reported to some 200-250 interested parties through our “ConCAss” network). We argued, for example, that no single definition of manufacturer is possible given the wide ranging nature of the products and installations regulated. We have questioned the wisdom about being so specific, and therefore inflexible, in the obligations conferred on different economic operators. The Commission, however, remains convinced of the rightness of its approach and it has received broad support for it from other Member States.

2. How to respond

When responding, please state whether you are responding as an individual or representing the views of an organization. If responding on behalf of an organization, please make it clear who the organization represents and where applicable, how the views of members were assembled.

A copy of the Consultation Response form is enclosed at Annex D. An electronic version is also available at <http://www.dti.gov.uk/consultations/>

We would prefer responses by e-mail, but you may also respond by letter or fax to:

Ana Nicola
Office of Science & Innovation
Department of Trade & Industry
Bay 280
151 Buckingham Palace Road
London SW1W 9SS
Tel: 020 7215 1573
Fax: 020 7215 1340
E-mail: <mailto:new.approach@dti.gsi.gov.uk>

A list of organizations already consulted and those we intend to consult as part of this process is in the hypertext links in Annex C. We would very much welcome suggestions of others who may wish to be involved in this consultation process.

Additional copies

You may make additional copies of this document without seeking permission. The documents for this consultation are downloadable electronically from the DTI website:

<http://www.dti.gov.uk/consultations/>

Printed copies of the consultation document can be obtained from:

DTI Publications Order line

ADMAIL 528

London SW1W 8YT

Tel: 0845 015 0010

Fax: 0845 015 0020

<http://www.dti.gov.uk/publications>

Other versions of the document in Braille, other languages or audio-cassette are available on request.

3. Confidentiality & Data Protection

Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). If you want any information that you want treated as confidential, please be aware that, under the FOIA, there is a statutory code of practice with which the public authorities must comply and which deals, among other things, with obligations of confidence.

In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your data will not be disclosed to third parties.

4. Help with queries

Questions about the policy issues raised in this document can be addressed to:

Name: Richard Lawson (general matters, market surveillance, CE Marking)

Team: Office of Science & Innovation
Department of Trade & Industry
151 Buckingham Palace Road
London SW1W 9SS

Tel: 020 7125 1469

Email: <mailto:richard.lawson@dti.gsi.gov.uk>

Name: Ms Radhika Sriskandarajah (accreditation, conformity assessment, notified bodies)

Team: Office of Science & Innovation
Department of Trade & Industry
151 Buckingham Palace Road
London SW1W 9SS

Tel: 020 7215 2913

Email: <mailto:radhika.sriskandarajah@dti.gsi.gov.uk>

If you have comments or complaints about the way this consultation has been conducted, these should be sent to:

Kath McKinlay
Better Regulation Team
Department of Trade & Industry
1 Victoria Street
London
SW1H 0ET

E-mail: <mailto:Kathleen.McKinlay@dti.gsi.gov.uk>

Tel: 020 7215 2811

Fax: 020 7215 2235

A copy of the Code of Practice on Consultation is in Annex B.

5. What happens next?

The final date for the closure of this consultation is 1 June 2007. The Government response to the consultation should be published on the DTI website within 3 months of the close of this consultation.

6. Consultation questions

Please respond to questions only if applicable. These are repeated in the Consultation Response Form.

Question 1: Accreditation. Does the framework for Accreditation meet the objective of providing sufficient confidence to the market that conformity assessment bodies are meeting the relevant harmonised standards? How might you improve the framework if it does not?

Question 2: Accreditation. Do you see any significant barriers to having a directly applicable Regulation on Accreditation?

Question 3: Accreditation. Do you have any concerns about the definition of Accreditation in the regulation? Do you think it captures the work your Accreditation organisation presently does?

Question 4: Market Surveillance. The Commission's perception is that there needs to be greater clarity as to what is expected of Market Surveillance and other public authorities to ensure more active and effective regulation of the Internal Market. What is your perception and would these proposals help to achieve this objective?

Question 5: Market Surveillance. The Commission is concerned at the apparent uneven levels of enforcement across Member States. Do you perceive that a strengthened framework for Market Surveillance will benefit the UK?

Question 6: Market Surveillance. (This is a question mainly for Market Surveillance practitioners and others in the public services but the opinions of all would be welcome.)

Our perception - based on our experience in the New Approach regulated sectors - is that some of the other important features of the proposals are primarily about confirming what Market Surveillance authorities ought to be doing whilst strengthening mechanisms for co-operation. What is your perception based on your experience?

Question 7: Market Surveillance. There are important new provisions on Border Controls that would develop the position as it presently stands under European Law (Regulation 339/93). These include placing new duties on Customs authorities in respect of non-compliant goods. Is the imposition of these new duties on Customs authorities justified to strengthen the provisions in Regulation 339/93 and is the frontier an appropriate place to intercept non-compliant goods from outside of the EU?

Question 8: Obligations of Economic Operators. The Commission believes that in the Global Economy, the pattern of responsibilities and interdependence of everyone in the supply chain means that one needs to spell out everyone's obligations in the way that it has done. What is your perception? Has the Commission developed a rational allocation of responsibilities and rational proposals on good working practices? What would be the impact on your business activity?

Question 9: Conformity Assessment. The Commission has tried to bring forward provisions that encapsulate all the key conformity assessment procedures in use in the world – from which those negotiating specific Directives in future would choose the ones appropriate to their sector. This does not assume that specific Directives may not include provisions to address specialised cases where justified. Has it succeeded – is your preferred method of conformity assessment included?

Question 10: Notified Bodies. Are the expectations of Notified Bodies and other Conformity Assessment bodies well-defined and are the proposed arrangements for regulating them satisfactory? If not, how might they be improved?

Question 11: Instruments. Is the interaction between the Regulation and Decision sufficiently clear for aspects on Notified Bodies and Accreditation?

Question 12: Safeguard Procedures. Will the proposal covering Safeguard Procedures make it operate more effectively?

Question 13: General. Do you have any observations or comments that might help the consultation process as a whole? Are there any particular additions or changes to the Regulation or to the Decision that you would like to see?

Glossary

Explanation of Accreditation

“Conformity assessment” is the demonstration that goods or services supplied, or systems and processes, meet the requirements specified or claimed for them. Conformity assessment bodies conduct such verification activities and the process used to ensure that they are competent is called “Accreditation.” Accreditation of conformity assessment bodies is undertaken against recognised international standards. While anyone can set up as an accreditation body, Government policy in the UK and most (but not all) other EU Member States is to recognise one body for the purpose. Government recognition of one authoritative accreditation body ensures good practice. This does not prevent other unrecognised bodies from trading. The UK Accreditation Service (UKAS) is the UK’s recognised National Accreditation Body. Its competence is ensured through a process of peer assessment undertaken between the different Accreditation Bodies of Europe.

Explanation of Market Surveillance

Market Surveillance is the expression used in the Proposal and more generally to refer to the whole process (including enforcement) by which the public services charged with these responsibilities across the European Union should ensure that products comply with the requirements of harmonising European product legislation.

Explanation of the Regulation

In this case to be adopted by the Council in conjunction with the European Parliament, the Regulation will be a general measure that is binding in all its parts. Unlike directives which are addressed to the Member States, and decisions, which are for specified recipients, regulations are addressed to everyone. The Regulation will be directly applicable, which means that it creates law which takes effect as law in all the Member States in the same way as a national instrument would do, without any further action on the part of the national authorities.

Explanation of the Decision

In this case to be adopted by the Council in conjunction with the European Parliament, the Decision will be addressed to the institutions of the European Union and takes effect against them. Unlike the Regulation, it will have no direct effect in a Member State. It is intended to become a “self-denying ordinance,” aiming to constrain the institutions from departing from its framework unless this can be well justified in the case of a particular sector.

A decision is:

- an individual measure, and the persons to whom it is addressed must be specified individually, which distinguishes a decision from a regulation,
- binding in its entirety.

Annex A

Impact Assessment

1. Title of Proposals

Proposal of the European Parliament and of the Council on for a Regulation setting out the requirements for Accreditation and market surveillance relating to the marketing of products (COM (2007) 37 final) and Proposal of the European Parliament and of the Council on for a Regulation for a Decision on a Common Framework for the Marketing of Products (COM (2007) 53 final).

The Proposals are currently at the pre-negotiating/negotiating stage.

Please see the **European Commission's Impact Assessment** at http://ec.europa.eu/enterprise/newapproach/review_en.htm. Please also see Response charts for “Consultation on the Review and extension of the New Approach” using the same link.

We attempt here to summarise certain important features of the Impact Assessment.

The Impact Assessment evaluates options for major areas of the Proposals and reports on the views expressed in its public consultations. It considers options for not taking action, for taking non-regulatory action and for taking a regulatory approach. In regard to the features of the Proposals where this is appropriate, it evaluates different regulatory options. See its Summary of Options after part 4.5 of the document.

It should be recalled the original Review of the New Approach, published in 2003, concluded that the Approach remained a fundamentally sound one but the certain features needed enhancement in their implementation. Accordingly the process has been inherently selective not addressing areas where no action was considered necessary or where action was to be taken by other means than the Review process. Much of this stage of the process is therefore about deciding on the balance between regulatory and non-regulatory action, and on the right form of regulatory action.

One important feature is that the scopes of key provisions vary. The Accreditation provisions in the Regulation Proposal are of very wide scope and attempt to align the regulated and non-regulated conformity assessment activities. The Market Surveillance provisions of the Proposal are also of wide scope but the list of exempted legislation is longer.

Another important consideration is that Commission has come to the conclusion that the costs and benefits cannot be quantified because the scope of the measures is so broad – see Section 5.1 (and - it could have added - the scopes of the provisions vary, as referred to immediately above). In the consultation, those responding have given their views on whether costs and benefits would increase but have in most instances not been able to quantify them. As you will note, the

responses are largely favourable to the courses of action the Commission has decided to Propose – often strongly so.

It also has to be kept in mind that none of the provisions of the Decision will apply until specific legislative Proposals are brought forward and that would be the feasible time to evaluate whether their costs and benefits could be quantified – sector by sector – the more so as notwithstanding the strictures on the importance of harmonisation some, limited degree of variation to take account of sectoral circumstances seems likely in practice.

Annex B

The Consultation Code of Practice Criteria

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
3. Ensure that your consultation is clear, concise and widely accessible.
4. Give feedback regarding the responses received and how the consultation process influenced the policy.
5. Monitor your Department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.
6. Ensure your consultation follows better regulation practices, including carrying out a Regulatory Impact Assessment if appropriate.

The complete code is available on the Cabinet Office's web site, address <http://www.cabinetoffice.gov.uk/regulation/consultation/index.asp>

Annex C

List of organizations already consulted

Organisations consulted via ConCAss:

ABS Group
Accreditation service for certifying bodies (Europe)
Advantica Certification Services Ltd
Airedale International Ltd
Allcord Ltd
Amtac Laboratories Ltd
Arrowhead Industrial Services
Asco Joucomatic Ltd
Association of British Certification Bodies (ABCB)
Association of British Healthcare Industries (ABHI)
Association of British Mining Equipment Companies (ABMEC)
Association of Manufacturers of Domestic Appliances (AMDEA)
Association of Manufacturers of Power Generating Systems (AMPS)
Association of the British Pharmaceutical Industry (ABPI)
ASTA BEAB Certification Services
AstraZeneca UK Ltd
Astrium Products
Atlantic Bridge Ltd
AV Technology Ltd
Avon Protection Systems
BM Polyco Ltd
Bolle Safety
Boots Plc
British Aerosol Manufacturers Association (BAMA)
British Approvals Board for Telecommunication Ltd
British Approvals Service for Cables
British Approvals Service for Cables (BASEC)
British Association of Leisure Parks, Piers & Attractions
British Cables Association
British Ceramic Confederation
British Chambers of Commerce
British Coatings Federation
British Coatings Federation
British Compressed Air Society, The
British Electrotechnical and Allied Manufacturers Association (BEAMA)
British Electrotechnical Approvals Board
British Equestrian Trade Association
British Fire Protection Systems Association
British Fluid Power Association

British Fluid Power Association
British in Vitro Diagnostics Association (BIVDA)
British Inspecting Engineers Ltd
British Marine Federation
British Pump Manufacturers Association (BPMA)
British Retail Consortium
British Safety Council
British Safety Industry Federation
British Standards Institution
British Toy & Hobby Association, The
BSI Product Services
Bureau Veritas Consumer Products Services UK Ltd
Bureau Veritas Inspection Ltd
Bureau Veritas Quality International (BVQI)
Campden & Chorleywood Food Research Association Group
Cast Metals Federation
CCQS UK Ltd
CEHOG Consumer Protection Sub-Group
Certification International (UK) Ltd
Chartered Institution of Building Services Engineers, The
Chartered Quality Institute (CQI)
City University London
Civil Aviation Authority
Coherent Tech Ltd
Confederation of British Industry (CBI)
Conformance Services Ltd
Consumers Association Research & Testing Centre (Which)
Cosmetic, Toiletry & Perfumery Association, The
Det Norske Veritas London
Directives Advisory Service
Edmund Nuttall Ltd
Electrical Contractor's Association
Electrical Distributor's Association
Electrical Installation Equipment Manufacturers' Association
Elfab Ltd
EMC Test Laboratories Association
Engineering and Machinery Alliance (EAMA)
Engineering Employers Federation (EEF)
Engineering Equipment and Material Users Association (EEMUA)
ETL SEMKO
Expert Ease International
FBE Management Ltd
Federation of Small Businesses
Fire Brigades Union
Fire Extinguisher Trade Association (FETA)
Gambica Association Ltd

GlaxoSmithKline
Global Certification Ltd
Graham Hart (Process Technology) Ltd
Greenham
Halfords
Hartley Jones Innovation Ltd
Health Protection Agency
ICOM Energy Association
INNOGY
INSPEC
Institute of Occupational Medicine
Institution of Mechanical Engineers
Intellect
International Lift & Escalator Consultants
International Powered Access Federation
International Register Certified Auditors
Intertek Labtest UK limited
ISOQAR Limited
JJW Consultants Limited
John Liscombe Ltd
Laboratory of the Government Chemist
Lift & Escalator Industry Association
Lighting Association Ltd
Lighting Industry Federation
Linx Printing Technologies Plc
Lloyds Register Quality Assurance Limited
Lloyd's Register Verification Limited
Lubrizol Ltd
M W Kellogg Ltd
Maritime & Coastguard Agency
METCOM
MICA Associates
Mitsui Babcock
More Than Safety Ltd
National Association of Goldsmiths
National Physical Laboratory (NPL)
National Quality Assurance Ltd
National Security Inspectorate
Nemko Ltd
Nottingham Business School
Nuclear Electric
Occupational Safety and Health Editorial
Office of Solicitor to the Advocate General
Ormathwaites Consultants Limited
Pall Corporation
Panasonic UK

PERMA Knowledge
Portable Electrical Tools Manufacturer's Association (PETMA)
Quality Scheme for Ready Mixed Concrete
Road Haulage Association Ltd
Rotating Electrical Machines Association
RWE Npower Plc
Safety Assessment Federation (SAFED)
Safety Consultancy, The
Samsung Electronics ECC
SATRA Technology
Security Systems and Alarms
SGS United Kingdom Limited
Small Electrical Appliance Marketing Association
Society of British Gas Industries (SBGI)
Society of British Water Industries
Society of Maritime Industries
Society of Motor Manufacturers and Traders
Spirax Sacro Ltd
Star Refrigeration
Technology International (Europe) Ltd
Texaco Ltd
The European Association of Internal Combustion Engine Manufacturers
Trade Union Congress
Trading Standards Institute
TRL Compliance Services Ltd
TUV Product Service Ltd
UK Cares
UK Cleaning Products Industry Association
UK Weighing Federation
Underwriters Laboratories (UK) Ltd
Unicorn Group Ltd
University of Oxford
University of Portsmouth
VT Halmatic Ltd
WEB Processing (M/C) Ltd
Welding Institute
Yacht Brokers and Designers and Surveyors Association (YBDSA)

Representatives to the DTI Chaired Project Team (established under the aegis of the inter-departmental Standards Policy Committee):

Department for Communities and Local Government (DCLG)
Department for Environment and Rural Affairs (DEFRA)
Department for Transport
Food Standards Agency

Health and Safety Executive
HM Revenue and Customs
LACORS
Medicines and Healthcare Regulatory Agency (MHRA)
National Weights and Measures Laboratory (NMWL)
Office of Communications (Ofcom)
Patent Office
United Kingdom Accreditation Service
Vehicle Certification Agency

We intend to consult the following organizations

We intend to consult more widely, e.g. the Small Business Service's list of organizations that want to be consulted about European Union Proposals, and add those who wish to be consulted to the ConCAss list.

In addition, we intend to consult those on the extensive contacts lists that DTI maintains for each piece of sectoral New Approach legislation. This will include amongst others, trade associations, Notified Bodies, businesses, individuals, professional bodies and Market Surveillance practitioners.

Annex D

Consultation Response Form

CONSULTATION ON PROPOSALS FOR A REGULATION ON ACCREDITATION AND MARKET SURVEILLANCE AND A DECISION ON A COMMON FRAMEWORK FOR THE MARKETING OF PRODUCTS

The closing date for this consultation is Friday, 1 June 2007

You may find it helpful to set out your responses to the Consultation using this Response Form.

Name _____

Organisation (if applicable) _____

Address _____

Return completed forms to:

**Ana Nicola
Sustainable Development and Regulation Directorate
Department of Trade and Industry
151 Buckingham Palace Road
London
SW1W 9SS
Tel: 020 7215 1573
Fax: 020 7215 1340
E-mail: <mailto:new.approach@dti.gsi.gov.uk>**

Question 2: Accreditation. Do you see any significant barriers to having a directly applicable Regulation on Accreditation?

Comments

Question 3: Accreditation. Do you have any concerns about the definition of Accreditation in the regulation? Do you think it captures the work your Accreditation organisation presently does?

Comments

Question 4: Market Surveillance. The Commission's perception is that there needs to be greater clarity as to what is expected of Market Surveillance and other public authorities to ensure more active and effective regulation of the Internal Market. What is your perception and would these proposals help to achieve this objective?

Comments

Question 5: Market Surveillance. The Commission is concerned at the apparent uneven levels of enforcement across Member States. Do you perceive that a strengthened framework for Market Surveillance will benefit the UK?

Comments

Question 6: Market Surveillance. (This is a question mainly for Market Surveillance practitioners and others in the public services but the opinions of all would be welcome.) Our perception - based on our experience in the New Approach regulated sectors - is that some of the other important features of the proposals are primarily about confirming what Market Surveillance authorities ought to be doing whilst strengthening mechanisms for co-operation. What is your perception based on your experience?

Comments

Question 7: Market Surveillance. There are important new provisions on Border Controls that would develop the position as it presently stands under European Law (Regulation 339/93). These include placing new duties on Customs authorities in respect of non-compliant goods. Is the imposition of these new duties on Customs authorities justified to strengthen the provisions in Regulation 339/93 and is the frontier an appropriate place to intercept non-compliant goods from outside of the EU?

Comments

Question 8: Obligations of Economic Operators. The Commission believes that in the Global Economy, the pattern of responsibilities and interdependence of everyone in the supply chain means that one needs to spell out everyone's obligations in the way that it has done. What is your perception? Has the Commission developed a rational allocation of responsibilities and rational proposals on good working practices? What would be the impact on your business activity?

Comments

Question 9: Conformity Assessment. The Commission has tried to bring forward provisions that encapsulate all the key conformity assessment procedures in use in the world – from which those negotiating specific Directives in future would chose the ones appropriate to their sector. This does not assume that specific Directives may not include provisions to address specialised cases where justified. Has it succeeded – is your preferred method of conformity assessment included?

Comments

Question 10: Notified Bodies. Are the expectations of Notified Bodies and other Conformity Assessment bodies well-defined and are the proposed arrangements for regulating them satisfactory? If not, how might they be improved?

Comments

Question 11: Instruments. Is the interaction between the Regulation and Decision sufficiently clear for aspects on Notified Bodies and Accreditation?

Comments

Question 12: Safeguard Procedures. Will the proposal covering Safeguard Procedures make it operate more effectively?

Comments

Question 13: General. Do you have any observations or comments that might help the consultation process as a whole? Are there any particular additions or changes to the Regulation or to the Decision that you would like to see?

Comments