

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]**

**Government Response to the
Public Consultation**

November 2007

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SURVEILLANCE AND A DECISION ON A COMMON FRAMEWORK FOR
THE MARKETING OF PRODUCTS
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GOVERNMENT RESPONSE TO CONSULTATION

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Executive Summary and Background

In March 2007 the Government published a consultation document seeking views on the proposals adopted by the European Commission on 13 February 2007 and which are currently under consideration by the European Parliament and the Council of Ministers.

The purpose of this consultation was 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.

The Consultation featured two separate proposals that needed 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 have the objective to provide a common framework for the existing infrastructures for accreditation for the control of conformity assessment bodies, and market surveillance for the control of products and economic operators, by reinforcing and extending what exists and not weakening existing instruments. They also set out agreed policy for the revision of existing product related Community harmonisation legislation, where necessary, and for the development of future product related legislation

The proposals are very much within the framework of the overall Commission policy to promote simplification and better regulation as widely as possible. Taken together, they aim to improve the European Internal Market for goods by bringing forward transparent and harmonised proposals that can apply in as many sectors as possible.

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

<http://www.dti.gov.uk/innovation/strd/activity/page10936.html>

Full texts of the Regulation and the Decision can be found on the Europa website at:

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

Since the launch of the consultation, and following machinery of Government changes, the Department of Trade and Industry has been split into the Department for Business, Enterprise and Regulatory Reform (BERR) and the Department for Innovation, Universities and Skills (DIUS). Both Departments have policy responsibilities in the areas covered by the consultation, with BERR taking overall lead.

Both BERR and DIUS are very grateful for all the constructive responses received and consideration of all comments and suggestions has helped to inform UK negotiating priorities.

Responses Received

The consultation posed 13 questions about the proposals including an invitation for general comments about the Regulation, the Decision and the consultation process.

A total of 33 written responses to the consultation paper were received (see Annex A for details of respondents) and these broke down as follows:

Small to Medium Enterprise	4
Representative Organisation	14
Trade Union	0
Interest Group	0
Big Business	7
Local Government	1
Central Government	1
Other (eg. Consultant or private individual)	7

To support the consultation and to inform its negotiation position, BERR also drew upon comments received during 3 meetings with ConCass stakeholders, which took place on 7 February, 23 April and 20 July. ConCass is a list of stakeholders that we can consult by email or in meetings that was set up to replace the National Forum, a body that dealt with policy issues on standards for Conformity Assessment and Quality Management Systems. It is formed by those with a professional interest in technical regulations (including Trade Associations, professional bodies and business) and therefore, has a clear focus on the New Approach Review. It is an important

consultation mechanism for BERR on both the Regulation and the Decision Proposals.

A New Approach Project Team has also been created under the aegis of the inter-departmental Standards Policy Committee. This Team, which is over 60 strong, represents all those central Government departments with an interest in these Proposals. Regular meetings have been held since February, which has helped to inform the UK negotiating position.

The following analysis of the responses to the consultation is structured around the questions posed in the consultation document. The Government's responses to the points raised are set out after each question.

Summary of Responses

The following analysis of the responses to the consultation is structured around the questions posed in the consultation document. The Government responses to the points raised are set out following each question.

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?*

The majority of respondents thought the framework provided confidence but some disagreed and there were a number of reservations expressed or improvements suggested.

1.1 Two respondents disagreed on the basis that the framework was anti-competitive: the cross-border market for services would be restricted as (1) there will only be one national accreditation body; and (2) that national accreditation body shall accredit others. This issue has been discussed at some length in Council Working Party meetings. Our policy is that National Accreditation Bodies (NAB) should not compete against each other in order to retain their authoritative status. The restriction on conformity assessment bodies using only the accreditation body in the area in which they were located was questioned as being an unnecessary restraint on trade, as all accreditation bodies have to meet an equivalent level of technical competence but may provide unequal service in terms of price, timescales, etc. Limiting choice of accreditation body is a consequence of smaller Member States believing it would undermine their NAB if the Conformity Assessment Bodies went elsewhere. It would also make it more difficult for them to establish and up-skill their own NABs. We support this position but take note of the comment on price and timeliness.

1.2 Two respondents felt that uniformity achieved through the medium of forums was better than using legislation to improve the accreditation process.

1.3 There may be alternative methods of achieving the objective of uniformity but the Regulatory Framework provides a structure that must be applied by all Member States that sets robust limits within which NABs must operate now and in the future. It will allay CAB concerns that there is no level playing field at the conformity assessment level.

1.4 Another alternative was proposed whereby an organisation within the EU community wishing to be accredited would follow a uniform process that culminated in a decision, taken by a higher level body, whether to accept. This would base accreditation on performance or proven work, like an audit but follow specifically the parameters set for accreditation.

1.5 This proposition appears to add another layer to the accreditation system and is thus more likely to complicate the system, raising questions

about the criteria to be used by this “higher body” and how these could be applied in a consistent way.

1.6 Areas thought to require amendment or that were subject to reservation included:

- Definitions and scope.
- Clearer explanation of the role of EA in providing a European network for national accreditation bodies.
- Less restriction on cross-border activities of national accreditation bodies when requested by conformity assessment bodies.
- Interpretation of standards [it can take time for an authoritative interpretation and in the interim conformity assessment bodies can differ in their interpretation] and more effort required to remove ambiguity in interpretation of standards.
- Accreditation assessors should be closely involved with the safety issues of the industry sector concerned.
- Bodies wishing to provide conformity assessment should be subject to obligatory requirements designed to maintain the necessary expertise and experience.
- Conformity testing, by accredited bodies, in non EU countries must be allowed to continue if the UK industry is not to be adversely affected.
- It is vital for Notified Bodies to have appropriate experience in their appointed field.
- The Commission needed to ensure a continued dialogue with all stakeholders to pursue greater harmonisation of such a framework on an international scale, and to ensure that compliance with the law by those operating within the Community Market did not put them at a competitive disadvantage.
- There needs to be consistency in assessment and approach between accreditation bodies of different Member States.

1.7 The areas thought to require amendment have been discussed and the UK proposed amendments on a number of these. The key issues have been scope and definition [widen and to international standards]; non-competition between NABs; the role of EA.

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

2.1 The consensus of respondents was that there were no significant barriers.

2.2 Some concern was expressed that newer Member States might lack the required experience and/or professional and technical expertise; and similarly that some organisations might struggle because of lack of experience and human resources. In addition one respondent had some unease that in the UK, with only one recognised national accreditation body, some delays might result and therefore disadvantage some organisations seeking

accreditation. Equally one respondent saw only having one recognised national accreditation body as an advantage. Two respondents felt the system worked as it currently stood and questioned the need for more regulation with the legal framework being set by the EU without it having to be transposed by the Member States.

2.3 We are pleased with the broad support for a European wide framework on accreditation and note the concerns over potential delays when the Instrument comes into force.

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?

3.1 A number of concerns and issues were raised.

The Regulation needed to be restricted to accreditation carried out according to recognised international and European standards. Otherwise less formal types of accreditation would unintentionally fall within the scope of the Regulation. A reference to the standards therefore needed to be included within the definition of accreditation.

The limitations in the scope of the Regulation (to the accreditation of conformity assessment of products) would exclude a significant number of accreditation activities currently carried out by UKAS from the legal framework. It was considered that this would result in a distortion of the market for conformity assessment.

There were a number of concerns over definition and clarity of definition.

- A definition of the minimal scope of accreditation was required otherwise Notified Bodies and other organisations carrying out official functions might become unduly restricted in their activities.
- Clarity was required as to what “third party attestation” covered and the definition should make clear that such third parties were nationally appointed and were members of EA.
- Accreditation required careful definition to avoid any confusion with terms such as Notified Body.
- The tasks a Conformity Assessment Body can perform needed to be defined.
- “Public Authority” needed to be defined [Article 4].
- Consistency was required in the way terminology and standards were interpreted and applied; and consistency of conformity assessment between different nations both within Europe and outside.

National Accreditation Bodies should publish annual reports on their monitoring activities.

Accreditation bodies need to be better equipped to undertake their work, in particular the quality of the assessor and assessment.

Article 6 should be deleted as it prevented the freedom of choice to use UKAS to accredit all facilities in various Member States.

Greater recognition should be given to manufacturers who had their own accredited laboratories for carrying out assessment to Harmonised Standards, in providing a presumption of conformity with the essential requirements of the pertinent Directive [Article 6].

Market surveillance should be proportionate [Article 6].

The formalisation of a single National Accreditation Body was desirable but the wording under Article 6 was too restrictive. The situations detailed in (a), (b) and (c) were tightly defined and conformity assessment bodies should not be so heavily restricted.

In respect of Article 6: EA needed a strong EAAB (advisory board of stakeholders) and a code of practice. The need for an 'observer' was also questioned because if the MLA worked properly there was no need for this requirement.

There was thought to be a conflict between Article 10 and Article 9.

In respect of Article 12 a respondent questioned whether EA was an organisation fit for purpose and how well it was resourced.

3.2 We agree with the fundamental concern regarding the scope and definition of accreditation in the European Commission's proposal and have worked with other Member States to limit the accreditation to which the Regulation applies so that it does not capture less formal accreditation. Our intention is to define accreditation according to the relevant harmonised standards e.g. EN45000 and ISO 17000. However our intention has been to widen the scope beyond products as retaining the reference to products creates a two tier system – one tier for products and one for other activities like management systems.

Some of the other points on definitions that responses have alluded to on consistency are noted.

With respect to the suggestion that NABs be required to publish annual reports, and that accreditation bodies being equipped to undertake their work, we concur that the requirements for NABs should be robust. The competence of NABs however is assessed to internationally recognised standards and covers these areas. The Regulation also contemplates that there will be information obligations on NABs to inform Member States of the details of their assessment and on the activities on which they may provide accreditation.

We believe that giving manufacturers' in-house accredited bodies greater recognition will move bodies at the conformity assessment level away from a level playing field and for this reason we do not support this suggestion. We recognise however the intention of this proposal.

We are pleased that there is support for a single National Accreditation Body but consider that the principle of non-competition between NABs is fundamental to ensure that NABs in each Member State are not undermined. The situation detailed in Article 6 permits cross-border cooperation between NABs when it is necessary.

The resourcing of EA, and the role of EAAB, is being considered outside the negotiations on the Regulation. We believe that this is the right approach and there are opportunities for us to influence this discussion.

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?*

4.1 There was general and widespread agreement that greater clarity is required and that market surveillance needed to be improved across the EU. There was a general acceptance that the Regulation Proposal would help to achieve this.

4.2 A Trade Association whilst agreeing with the question thought that the Commission should define levels of enforcement and how it should take place. A large business went further and suggested that there should be a framework for market surveillance that should be incorporated within each Directive.

4.3 We believe that this area should be left to the responsibility of Member States who have designated market surveillance professionals, skilled in risk assessments and with knowledge of national markets, rather than a Commission competence. We expect that the Regulation Proposal would lead to greater co-operation between Member States in areas like best practice which inevitably will lead to common standards of enforcement. The Regulation Proposal will have direct effect in law and will essentially negate the requirement to have too much detail written in the directives. The Commission views the market surveillance provisions as common requirements that could be introduced to significantly strengthen market surveillance across the Internal Market. These provisions though would not materially change the existing sectoral Directives. We support this view.

4.4 A Trade Association pointed to the practices of WELMEC which seeks to achieve consistent interpretations via voluntary guidelines which it considered a better approach than a general regulation.

4.5 Our view is that there is nothing in the Proposal to stop sectoral groups from subsequently devising their own guidelines in a similar way to WELMEC, but we also recognise that if this occurred in each regulated area it could potentially lead to yet more inconsistency and duplication. The objective of the Regulation Proposal is to promote the necessary consistency of approach required to strengthen market surveillance.

4.6 A Trade Association considered that there was insufficient planning of market surveillance both in the UK and the wider EU which leads to either duplication of under-enforcement.

4.7 We expect that greater co-ordination will be required from Member States. We therefore, intend to strengthen co-ordination in this area.

4.8 A Trade Association thought that definitions of 'serious risk' and 'non-compliance' were needed and stated that RAPEX concentrated more on hazard than risk.

4.9 We consider that the market surveillance authorities fully understand the definitions of serious risk and non-compliance. The point about RAPEX is noted although we consider it to be a useful tool.

4.10 The representative of many regulatory authorities agreed, but put forward a drafting change related to Article 14 where it wanted a specific reference to 'entering or placing on the market'. It was also concerned about the potential lack of criminal liability for importers that have non-compliant goods in their possession but prior to placing it on the market.

4.11 We think that the drafting of Article 14 should have the required effect. In terms of criminal liability for importers, the Commission has been attempting to make the definitions of 'making available' sufficiently broad but we will consider this point.

4.12 A consultancy thought that Public confidence would be higher in market surveillance (in an area enforced by HSE) if details of actions and outcomes were more public.

4.13 We consider that many enforcement actions are already in the public domain e.g. criminal prosecutions or the issuing of enforcement notices. However, caution is required particularly where cases have either yet to be tried or where a company's reputation could be materially damaged. For example, any information support system based on the Information and Communication System for Market Surveillance (ICSMS) would have a public section aimed at informing the business/public and a closed private area accessible only by market surveillance authorities with more detailed information on non-compliant products.

4.14 Some companies made the point that there are limited resources allocated in this area and the Regulation Proposal may require a large increase.

4.15 We recognise that this is an issue across the EU. Member States will need to address this and look at whether any best practice efficiency improvements can be put in place to alleviate the resource burden. In the UK, the Better Regulation Executive has been doing a lot of work with stakeholders in areas like risk, efficiency and prioritisation. We note the point.

4.16 A large business wished to see the development of a single point of contact within an economic operator to allow for better co-operation with the market surveillance authorities.

4.17 We understand that this is quite common practice in the UK. The point is noted.

4.18 One consultancy found the term 'surveillance' to be intimidating and preferred the use of a different term.

4.19 Our view is that economic operators and public authorities are used to dealing with the term 'market surveillance' and there would be little benefit from calling for a change.

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?*

5.1 Most respondents answered positively to this question. One Trade Association insisted this was conditional on market surveillance authorities accepting the relationship between directives and harmonised standards, applying harmonised risk assessment methods, and making a clear distinction between serious risk of injury and minor non-compliance.

5.2 UK enforcement practice is based on a proportionate approach, so the response to a product posing a serious risk will, in many instances, be different from one with a less serious non-compliance. However, all non-compliances can lead to an economic advantage which damages the competitiveness of rivals and it is therefore, right that powers be available to the market surveillance authorities. We note these points.

5.3 There were a number of comments about harmonisation with other Member States. One complained that the UK applies the full extent of the law when others do not. Another suggested that other Member States had much to learn from the UK model including the home authority principle as used by Local Authorities. One warned about the potential for conflicting results when different tests were used on the same products. One large business indicated the importance of a risk based approach to targeted market surveillance.

5.4 We note these comments. We believe that the Regulation Proposal will strengthen cross-border ties between Member States and that all will benefit from sharing experiences, and best practices. We fully support the

use of risk-based approaches to market surveillance which is in line with UK enforcement practices.

5.5 An institute representing enforcement professionals made reference to what it considered to be the depletion of resources for market surveillance and also bemoaned the loss of national accident and injury statistics.

5.6 We note both comments and recognise that all Member States will need to address these issues.

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?*

6.1 Not all respondents directly answered the question but those that did generally felt that the perception was correct.

6.2 The representative of many regulatory authorities considered that the Regulation Proposal was in line with current UK market surveillance practice. However, there was concern at the lack of focus on cross border co-operation which could see a Home Authority principle utilised across the EU where one Member State could intervene on behalf of another.

6.3 We view the development of a European-wide information support system, the extension of RAPEX and the other cross-border liaison initiatives, as factors that will help authorities across the EU share information and will help to identify responsible persons. This will naturally lead to much closer links between market surveillance authorities.

6.4 There were a number of comments that whilst agreeing with the perception claimed there was not a great deal of evidence that all Member States were meeting their obligations in this area. Many wanted closer harmonisation between Member States and one company wanted the Commission to take a more forthright approach with Member States with weak market surveillance practices. Two respondents said that there was even a lack of harmonisation within the UK system and one Trade Association who also commented on the fragmented nature of the UK market surveillance system thought that those authorities needed to co-operate better with each other at the national level.

6.5 One of the rationales for the Regulation Proposal is to strengthen market surveillance because of inconsistencies in the approaches of Member States, so we accept these comments. We consider that market surveillance co-operation should be enhanced and aim to develop mechanisms to support this.

6.6 A consultancy thought that there would be a disproportionate effect on SMEs particularly those without certificated management systems.

6.7 We believe that market surveillance activity should only be targeted at those companies suspected of non-compliance and in particular those suspected of taking commercial advantage from such non-compliance or those supplying unsafe goods. This will alleviate any threat of a burden on compliant businesses.

6.8 A Trade Association commented on the likely additional costs from enhanced market surveillance.

6.9 All the indications are that the costs will not be as high as the benefits that are expected to accrue from greater competitiveness and the enhanced safety of the public and workforce.

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?*

7.1 There was a mixed response from stakeholders with a marginally larger proportion supporting the principle that the frontier is an appropriate place to intercept goods from third countries. However, there was concern particularly from business that any border controls could impose: a) delays on time to market, and b) protectionism for domestic manufacture. Those supporting came from a range of trade associations, business and public authorities who saw value in targeting non-compliant goods at the frontier rather than once dispersed onto the market.

7.2 A Trade Association considered that Customs did not possess the relevant skills to assess the safety of goods. Another Trade Association commented that it could not see how it could work in practice and called for a simplified and pragmatic approach.

7.3 We agree with this assessment and have put forward our negotiating position based on the concept that Custom's role ought to be limited to that of co-operation and information exchange with the market surveillance authorities using risk profiling of its import data. This necessitates the creation of legally established gateways for information between the authorities. This would then play to the strengths of Customs in profiling/detaining and the market surveillance authorities in risk assessment and subsequent enforcement of non-compliant goods.

7.4 A consultancy commented on the resource that would be required to implement these provisions.

7.5 We note this comment.

7.6 A number of businesses and Trade Associations commented on the potential for there to be delays placed on goods passing through Customs procedures and that this could have a disproportionate effect on SMEs. One large business suggested that interception should be aimed at those goods where there is reasonable intelligence of non-compliance.

7.7 Any system that we implement in the UK would take full account of trade facilitation. Goods could only be intercepted using a risk-based targeting methodology which will limit the effect on trade flows. In addition, and where practicable, any system will be based both on activities at the border and (as with modern customs practices) on action at the point of destination.

7.8 A large business commented on the inconsistency between the concept of 'placing on the market' and the customs' frontier controls.

7.9 The Regulation Proposal seeks to ensure that surveillance is carried out on products at both the frontier and on the market. It is envisaged that the Regulation Proposal will provide the necessary powers for the customs and market surveillance authorities to co-operate with each other to target non-compliant goods and where necessary to ensure that they do not present a danger to the public.

7.10 A Trade Association saw the role of customs as essential and frontier action as more effective than other surveillance techniques. Another considered Regulation (EC) 339/93 should be strengthened.

7.11 The representative of many regulatory authorities welcomed a clearer role for the customs authorities and commented that this would need to be properly implemented in the UK and would require a significant change to current practices. A regulatory authority strongly supported the proposal for action at the frontier but did not consider customs to be best placed to make judgements on non-compliant goods. It considered, from its own experiences, that a system based on targeted risk profiling which relies on the HMRC database is a very effective method of sampling for non-compliant goods.

7.12 We agree with these comments.

7.13 One large business supported action at the frontier but stressed that it had to be the first port of entry and that procedures should be harmonised. An SME also supported this approach and called for a simplified role for customs.

7.14 We believe that harmonisation is important only in so far that all Member States will need to meet their obligations. It is important that Member

States should be allowed to develop their strategies based on the strengths of their own market surveillance and customs systems. It is equally important that any intervention is properly targeted and does not impact against trade in compliant goods.

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?*

8.1 A Trade Association voiced strong opposition to the requirement that manufacturers shall indicate their name and address in Article 7(6) and associated provisions in Article 9. It argued that importers needed to keep such details to themselves because this is commercially sensitive information. It also argued that it should be sufficient to supply the details of the importer itself. It supported this with analysis of how Article 7(7) would apply to European and non-European manufacturers. A company called for better drafting of 7(7) to emphasise proportionality of response.

8.2 This has been a basic feature of certain pieces of New Approach legislation since its inception and it appears to have worked satisfactorily. This concern has not been widely expressed and we cannot see a case for opposing this feature of the Commission's Proposal. We support the proportionality point.

8.3 A Trade Association called for the inclusion of a definition of "putting into use". It also broadly supported the overall proposed allocation of responsibilities between "Economic Operators" in Decision Chapter 2. Another called for greater clarity as to the meaning of the obligations. Another Trade Association called for action to ensure that there is clarity as to obligations where business is carried on "Free on Board" (FOB). A company and an individual called for more consistent use of terminology across European Commission Directorate Generals.

8.4 The Commission line on definitions is to include them only if the term is used in a Proposal. We think this is sensible. We note the support expressed. We will continue to consider the clarity point during the negotiations. However, the Decision is not legislation in its own right, so we consider that a fairly broad strategic approach is sensible given the wide range of products and situations that have to be regulated by the sectoral legislation. We will consider the FOB point but the same consideration applies. We agree on the desirability of consistency of drafting by the Commission.

8.5 The representative of many regulatory authorities said the Obligations of Economic Operators are useful but called for the obligations of Importers to be strengthened. It (and a company) also called for consistency of approach

between the market surveillance provisions of this legislation and the General Product Safety Directive (GPSD). A trade association argues that there should always be someone in the EU who takes full responsibility for the compliance of products of non-EU manufacture.

8.6 We initially argued that there should be no distinction between the obligations of manufacturers and importers but the Commission has taken the contrary point of view arguing that the distinction has to be recognized in the real world and that the law should place only those duties on importers that they can actually fulfil. A lot of concern has been expressed on the need for consistency of approach with GPSD. We will keep both issues under consideration in the negotiations.

8.7 A consultancy wonders whether the proposed distribution of responsibilities improved upon existing arrangements such as the Machinery Regulations' certificate of incorporation. However, three companies and a safety council are supportive of the approach.

8.8 The UK expressed similar scepticism about spelling out the responsibilities of the different persons in the supply chain. The Commission, however, received the support of many Member states for the approach. That has emerged in the Proposal. We will have to work within that framework to make it as satisfactory as possible. We note the expressions of support.

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?*

9.1 The overwhelming consensus was that the Commission had included all the key conformity assessment procedures.

Some reservations however were expressed or questions raised:

- the issue of non EU countries not allowing other countries to approve products to their standards needed to be addressed;
- how would non EU imports of manufactured goods not subject to the Directive be dealt with and how the Directive would be enforced in respect of these goods;
- up-to-date technical data showing conformity to all relevant directives was suggested as alternative to the mandatory involvement of third parties and as an alternative to market surveillance with the involvement of a third party (for example as foreseen in Module A1 and Module A2);
- greater clarity was required in respect of Article 19 in describing when market intervention would be required; and

- all the methods of conformity assessment should be made available to all Directives (rather than only to specific Directives). The proposal intends to act as a menu for the legislator to choose from and the Module applied for a Directive will depend on the product(s) it covers. We believe that a risk based approach is a sensible one.

9.2 We are pleased that there was broad support for the provisions on conformity assessment and notification process in the Decision.

The suggestion of up-to-date technical data as an alternative to third party assessment was considered. However the Commission's intention for the modules has been to introduce a risk-based approach. For this reason Module A allows the use of a Supplier's declaration of conformity (and thus allows the use of technical data). The higher risk products require third party bodies to provide consumers, the market and Member States' with confidence that the manufacturers' products are compliant and safe.

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?*

10.1 An overwhelming majority of respondents expressed general content with definition of expectations.

Certain areas required further clarification:

- Requirements for independence;
- Minimum scope of accreditation;
- Expectations of Conformity Assessment Bodies compared to Notified Bodies; and
- Overlap between the provisions in the Decision and the Regulation;

while there was some disagreement, or questioning of, the need for some requirements:

- Notified Bodies to be capable of carrying out all tests as this was considered to be unduly restrictive;
- Applicants for Notified Body status to submit an accreditation certificate with the application;
- Two month waiting period before Notified Bodies are allowed to operate;
- Regulation to define accreditation criteria;
- Decision Article 25(3) as it was felt there already existed harmonised standards that defined accreditation criteria; and
- Notified bodies not representing parties engaged in the use of the products they assess as that would prevent certain bodies from being a Notified Body.

Several respondents expressed concern about consistency:

- of assessments undertaken by Notified Bodies (test results for the same product carried out by different Notified Bodies produced variable results); and the need for
- forums to promote consistency of application of the regulatory mechanisms.

Further requirements:

- A comprehensive and transparent system for dealing with questions of interpretation as it was felt that without it no common EU understanding would be possible;
- Notified bodies must be accredited; and
- Regulation requires a rigorous and transparent peer evaluation system.

The arrangements for regulation were open to dispute: this needed to be more specific and defined.

10.2 We are pleased that the provisions on Notified Bodies are acceptable in the main but agree that we need to clarify and/or amend the detail of these provisions.

Independence has raised concerns and there is a will to apply this criterion (and others) more consistently.

We believe that there is a clear demarcation between expectations of CABs compared to NBs; in particular that NBs do not need to be accredited. We agree that both the Decision and Regulation need to be aligned to avoid confusion, particularly in respect of definitions.

We acknowledge that NBs do not need to be capable of carrying out all tests but the Commission explained that the thinking behind the provision is to avoid 'post box' NBs. The intention, which we support, is to prevent NB sub-contracting *all* activities.

We initially supported the removal of the two month waiting period but the Commission explained that the intention was to allow it time to consider notifications. Once the notification was approved there would be no problems for Member States or the CAB seeking notification. It would be far more detrimental for the CAB if it started its activities as a NB only to find that it was to be de-notified. On this basis we support the Commission.

We accept that there is a lack of consistency in the assessment undertaken by NBs. The link to accreditation aims to address this by ensuring that CABs, including NBs, are equally competent in the EEA. The Decision however does not make accreditation mandatory.

We support this position.

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

11.1 The majority of respondents considered that the interaction between the Regulation and the Decision is sufficiently clear for aspects on Notified Bodies and Accreditation. Some added a proviso that further guidance would be needed.

11.2 An SME stated how important it was that there is consistency and no possibility for misreading or misinterpretation of the requirements. A large business pointed out that the Proposals will raise many questions during the first 5 years and that it was important the responses enhance the understanding of the provisions by business. These points are noted.

11.3 A large business considered that the use of a Regulation and a Decision only served to confuse. Business needed to know that Notified Bodies are acting uniformly and also believed that market surveillance authorities should be governed by the same rules i.e. professional accreditation in the sphere being investigated.

11.4 Our view is that market surveillance officers are professionally trained and qualified to enforce a large range of legal instruments and it is not realistic to expect each official to be accredited for sector expertise as well. Where there are requirements for example to assess the compliance of goods with the legal requirements of the legislation then market surveillance officers have recourse to use competent sector expertise in either the public or private sector (e.g. accredited laboratories).

11.5 A representative organisation thought there was unnecessary overlap and considered that the Decision should give guidance on when a future directive should use Notified Bodies with the requirements for that body then being wholly contained within the Regulation.

11.6 We note the point about requirements for Notified Bodies being in the Regulation Proposal rather than the Decision Proposal. However, we believe that it sits better in the Decision Proposal because, unlike accreditation, it does not require the legal basis to be strengthened.

11.7 A consultant raised the issue that the accreditation standards had not been formally harmonised and do not cover the whole range of the legal requirements for Notified Bodies.

11.8 We accept these points. The Commission is to formally harmonise the relevant accreditation standards. On the second point, our negotiation position is to amend the definition of accreditation to take account of both the requirements set by the accreditation standards as well as any 'additional requirements'. We believe that this will take account of those requirements placed on Notified Bodies that fall outside of the relevant standards.

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

12.1 There was a lot of support for the Chapter 5 of the Decision – Safeguards Procedures. Within the framework of that perception, some contributors took the opportunity to voice concerns about how the current RAPEX systems works – are some of the market surveillance authorities too unfamiliar in regard to the products they notify and therefore too ready to notify them to the detriment of the reputation of e.g. the toy industry? Regarding Chapter 5, some responding considered that there was a need for a sense of proportion; a need to avoid undue costs; and a need for proper means of redress: perhaps the General Product Safety Directive offered a good model. Also, could the procedures for making information on safeguard actions available to Notified Bodies be improved? There was also some perception that, in spite of the detailed nature of the provisions, there was still scope for them to be applied inconsistently between Member States.

12.2 We welcome the support expressed for Chapter 5. We think that its considerable length is probably necessary to achieve the Commissions' laudable better regulation aim of ensuring that as many issues are dealt with at Member State level as possible and that only those that really need to be dealt with at EU level are referred accordingly. We take note of the other points made and will see what we can do to address them in the context of the EU negotiations.

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?*

13.1 Will it be quicker to negotiate the Decision Proposal than the Regulation Proposal?

13.2 We cannot be sure but it is our currently perception that neither will be finalised until the other has also been agreed.

13.3 There should be opportunities to rectify non-compliant products imported from outside the EU. The legislation should ensure that these arrangements are consistent between Member States.

13.4 We note this point.

13.5 Expression of support for UK position.

13.6 Noted.

Next Steps

We are pleased that in general terms the consultation exercise has confirmed the UK negotiation stance.

The UK has reserved its position and the Proposals have a Parliamentary Scrutiny reserve in place. In the meantime work continues in both the Council Working Party and the European Parliament.

The negotiations will continue and the BERR-lead negotiation team will use these responses and continue to consult with stakeholders in both Government and the private sector to inform its position as matters progress.

ANNEX A LIST OF RESPONDENTS

Alan Wills

Association of British Certification Bodies (ABCB)

Association of Manufacturers of Domestic Appliances (AMDEA)

Astrium Satellites

Atco-Qualcast Ltd (Bosch Group)

Atlantic Bridge Limited

British Approval Service for Electrical Equipment in Flammable Atmospheres
(Baseefa (2001) Ltd))

British Electrotechnical and Allied Manufacturers' Association (BEAMA)

British Toy & Hobby Association

BSI Product Services

Chevron Ltd

Construction Products Association

David Burdett

Electrical Safety Council

EQUITOY (formerly British Toy Importers Association)

Hewlett-Packard Ltd

Jerry Robertson

John McDonald

Local Authorities Coordinators of Regulatory Services (LACORS)

Lighting Association

Medicines and Healthcare products Regulatory Agency (MHRA)

Nemko Ltd

Oil Firing Technical Association (Oftec)

Peter Burt

Royal Yachting Association (RYA)

SKC Ltd

Society of Motor Manufacturers and Traders Limited (SMMT)

Suffolk County Council

Tandberg Television

Trading Standards Institute (TSI)

United Kingdom Accreditation Service (UKAS)

UK Cleaning Products Industry Association

UK Metering Forum

Vivid Imaginations Ltd