E U R O P E A N E C O N O M I C A R E A

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O F T H E E F T A S T A T E S

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SUBCOMMITTE I ON THE FREE MOVEMENT OF GOODS

EEA EFTA COMMENTS ON THE REVISION OF THE NEW APPROACH

These comments are made by Iceland, Liechtenstein and Norway (the EEA EFTA States) and are supported by Switzerland. The comments refer to N529 rev. 2. "Elements for a horizontal legislative approach to technical harmonisation."

1. The objectives of the review

The EEA EFTA States recognise the New Approach as an important tool for the functioning of the Internal Market and as a good example of co-regulation. The New Approach Directives play an important role in the effort to reduce trade barriers in Europe, and to ensuring that safe products are placed on the market. The CE marking system is widely recognised.

However, we agree that several elements of the New Approach need to be improved to enhance competitiveness of businesses, while safeguarding the interests of consumers, workers and the environment. The right balance must be struck, in light of better regulation.

A clearer framework for accreditation is required. We need to ensure that notified bodies are competent. Market surveillance within the Internal Market and along its external borders needs to be improved. Strengthening the credibility of the CE mark is crucial. It must be recognised that the CE-mark is no longer an instrument for manufacturers and market surveillance authorities only. It should be recognised that the CE mark is relevant also for consumers, and its meaning should be clarified to them.

2. The choice of the legislative approach to a new horizontal act

Reference is made to the discussions during the SOGS meeting on 30 January 2006. The EEA EFTA States consider that it is important to recall the objectives set out in the communication from the Commission to the European Parliament and the Council, Com (2005/535) "A strategy for the simplification of the regulatory environment". The communication stated that "Replacing directives with regulations

can, under certain circumstances, be conducive to simplification, as regulations enable immediate application, guarantee that all actors are subject to the same rules at the same time, and focus attention on the concrete enforcement of EU rules". The potential for improving the New Approach by choosing a regulation as the legal form for the new horizontal act should be analysed with these objectives in mind.

3. Point 5 – Conformity assessment bodies/notified bodies

Point 5.2 establishes the use of accreditation as one of the main tools for assessing and monitoring Conformity Assessment Bodies (CABs). The EEA EFTA States support the proposal that notifications of a CAB should be accepted when accreditation has not been demanded, in duly justified cases only.

In Point 5.2, it is proposed that Member States ensure that notified CABs continuously meet the relevant requirements. The EEA EFTA States consider that this should apply to all CABs, whether they were notified before or after the entry into force of a revised New Approach. As many CABs as possible should be accredited. A system *de facto*, requiring accreditation only for CABs designated after the entry into force of a revised New Approach, runs the risk of undermining confidence in the CE mark. It would also imply unequal competition between old and new CABs in the market place for conformity assessment.

Thus, the EEA States should be obliged to review non accredited CABs to ensure that they continuously meet the relevant requirements. Furthermore, the use of accreditation should be the main rule during reviews. A transitional period may be agreed at European level to ensure that as many CABs as possible are accredited. The proposal for a new horizontal act should reflect these suggestions.

We welcome the clarification in point 5.3, that the essential requirements for designating authorities listed in new Annex 3 only apply when Member States do not make use of formal accreditation. We agree that designating bodies which do not use accreditation as a tool for assessing and monitoring CABs, should be subject to conditions that are as stringent as those established through accreditation. This is important for product safety and trust in the CE-mark. It is our understanding that the requirements in point 5.3 are not applicable to the notifying authorities/ministries, if these are not the same as the designating authorities.

In Annex 3 paragraph 3, it is stated that the designating authorities shall not disclose confidential information about a CAB without its consent, except in cases where this is foreseen by law. Could this create problems, e.g. when a market surveillance authority of another state is investigating a particular case and needs information about a certain CAB?

It is important to ensure common understanding of relevant European standards among CABs. We therefore support the proposal contained in Annex 4 paragraph 7 on the CABs' involvement in standardisation activities.

4. Point 6 – Accreditation

The EEA States should recognise accreditation as a public authority activity.

Close links between European Co-operation for Accreditation (EA) and the Commission and the EFTA States are essential for the functioning of the accreditation system. We support the proposal that the EEA States recognise the EA and ensure that their national accreditation body is a member of EA. We furthermore support the proposal that the accreditation body shall participate in regular peer evaluation, in accordance with the relevant part of the Multi Lateral Agreement, and respect and implement the decisions taken by the EA. We do, however, stress the importance of appeal procedures for peer evaluation decisions, and transparency in the way the procedures operate. We welcome the General Guidelines for the co-operation between the EA and the European Commission and EFTA, contained in Annex 5.

5. Point 7 – CE marking of conformity

N529 rev. 2 states "*Text to be established following the outcome of the consultation on draft Certif 2005-11"*. We find it appropriate to attach some comments to the draft Certif document.

We support the continued use of the CE mark.

We believe that the CE mark should continue to indicate that a product is in conformity with relevant EEA legislation and European standards, as implemented at national level. We, therefore, do not support an alternative that would differentiate the meaning of the CE mark according to the module that was used for the conformity assessment, i.e. whether third-party involvement is required or not. The choice of module is related to the risk assessment of the product, when legislation is prepared. Consequently, even if third-party conformity assessment is not required, consumers can still rely on a CE marked product being manufactured in accordance with EEA rules. In parallel, market surveillance must be strengthened, to create trust in the CE mark.

We think that the time has come to realise that the CE mark does not concern businesses and market surveillance authorities only. It also contains important information for consumers. It is, therefore, important that they understand its meaning. To this end, consumers need more information. However, an information campaign on the meaning of the CE mark directed towards consumers would have little meaning if it is not recognised at a European level that the CE mark also is the porter of a message to consumers.

Making the consumer understand that the CE mark means that the manufacturer has done all that can be done to ensure that the product meets all essential requirements of European legislation, will also contribute to cope with the problem of the proliferation of national, voluntary quality marks.

We recognise that a discussion is needed on means to better protect the CE mark, and on possible sanctions against breaches of the rules relating to the New Approach and

the affixing of the CE mark. Furthermore, we are of the opinion that we need to discuss whether the CE mark should be used on products that are not subject to identical technical requirements in all EEA States, due e.g. to different climatic conditions.

6. Point 8 - Market surveillance

Market surveillance is essential to ensure that New Approach directives are correctly applied. The principle of subsidiarity is highly relevant in this respect, but we have to recognize that the level of enforcement varies throughout the EEA. If we make the necessary improvements within the area of market surveillance, while respecting the principle of subsidiarity, we will contribute to safer products and a level playing field for businesses operating in the EEA.

We therefore endorse the need to establish essential requirements for a market surveillance system. Such a system should, in particular, ensure that infrastructures and human and financial resources are sufficient to ensure appropriate surveillance. It should also establish effective mechanisms for national and cross-border communication and coordination, between market surveillance authorities, and with customs authorities. It is also important to adopt rules that ensure minimum sanctions applicable to infringements of European legislation, and ensure that they are transposed at national level.

We also support the idea of establishing a control mechanism, giving the Commission the role of ensuring compliance with the essential requirements on market surveillance.

Concerning the proposal to set up a single database for information and administrative cooperation purposes, we would like to point to the Internal Market Information project (IMI) carried out by DG Internal Market and Services. The IMI project will establish an information system (IT tool) that will link competent authorities in national administrations that are involved in managing or implementing free movement of goods in the Internal Market. IMI appears to have the potential of an appropriate and promising tool also with regard to market surveillance. Furthermore, we should avoid setting up parallel systems for administrative cooperation.

Finally, we encourage the Commission to organise mutual, joint visit programmes on market surveillance in selected product sectors.

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