EUROPEAN ECONOMIC AREA

STANDING COMMITTEE

OF THE EFTA STATES

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WORKING GROUP ON TECHNICAL BARRIERS TO TRADE

EEA EFTA comments to the EC Communication: Enhancing the Implementation of the New Approach directives

1. The EEA EFTA States welcome the communication of the EC Enhancing the Implementation of the New Approach Directives (COM (2003) 240(01)) as a necessary review after eighteen years of implementation. The proposed review is also necessary to strengthen the New Approach on the eve of the enlargement of the European Union.

2. The EEA EFTA States also find that the aspects of the New and the Global Approach selected for refinement in the Communication are the correct ones and, if the right decisions are now taken, go a long way to ensuring that the New Approach continues to function well as a harmonisation instrument on the Internal Market.

It must, however, be kept in mind that the CE Marking is the passport for industrial products to the Internal Market. Additional measures might be needed in order to strengthen this role, i.a. studies concerning the relationship between the CE Marking and voluntary quality marks.[1] Voluntary quality marks should not lead to a fragmentation of the Internal Market.

3. In relation to this, the EEA EFTA States find that it would have been an advantage if, in addition to the present aspects, some standards related aspects had been included in the review of the approach. CE Marking of conformity with legislative requirements in the Internal Market and the role of harmonised European Standards carrying a presumption of conformity with Essential Requirements of the New Approach Directives are intertwined and would benefit from being reviewed together.

[1] See concerning the position of the EEA EFTA States letter of September 8 2003 from the Liechtenstein Minister for Economic Affairs, Mr Hansjörg Frick, on behalf of the EEA EFTA States to the Italian Minister for Productive Activities, Mr Antonio Marzano, representing the Presidency of the European Council.

4. The EEA Agreement created the same legal basis for the New and the Global Approaches throughout the EEA, the 15 Member States of the EU and the three signatories to the Agreement from the EFTA side, Iceland, Liechtenstein and Norway, extending the Internal Market to these EFTA States. Switzerland has also been following the same policy as can be seen from the bilateral agreements between the EU and Switzerland. The policy under review is, therefore, of the utmost importance to the EFTA States. The present comments are from the EEA EFTA States but are endorsed by Switzerland.

5. The EEA EFTA States are fully prepared to provide further input into the process following this Communication and to support individual actions.

1. COMMENTS TO INDIVIDUAL POINTS

1.1 Enforcement and market surveillance

6. The EEA EFTA States agree that ensuring effective market surveillance throughout the EEA is important for the Internal Market. Different levels of market surveillance may undermine the credibility of the New Approach and the CE Marking among consumers and other interested parties. This in turn opens up the possibility of a re-fragmentation of the market through, among other things, voluntary marks. Ensuring a level playing field in market surveillance is therefore a central issue in enhancing the implementation of the New Approach directives, not least after the enlargement.

7. There is a need for intensified administrative co-operation among national market surveillance authorities in order to exchange information and encourage best practices. The EEA EFTA States furthermore believe that, as proposed in the Communication, it is necessary to define basic rules with which Member States would comply, including participation in the administative co-operation, exchange of information between market surveillance authorities and harmonizing sanctions for companies repeatedly misusing the New Approach system.

8. The EEA EFTA States prefer a horizontal directive establishing the basis for the Member States' obligations to market surveillance. This would have to be done without creating any uncertainty concerning obligations in the individual sector directives.

9. The EEA EFTA States also support the proposal to encourage market surveillance authorities to conclude co-operation arrangements on e.g. pooling of expertise, training and equipment with a view to ensuring the effective use of existing resources and avoiding gaps in market surveillance.The European Commission has a role to play in facilitating and assisting with the promotion of co-operation in the field of Market Surveillance.

1.2 The CE conformity marking

10. The CE Marking is the politically agreed passport to the EEA Area. The manufacturer or his representative puts the mark on his products thereby declaring that he has fulfilled all the requirements in all applicable New Approach directives, including the conformity assessment activities deemed to be necessary. This system was set up in order to ensure a free flow of industrial goods in the EEA area, contributing to the competitiveness of European industry, encouraging competition while ensuring safe products for the consumers without unnecessary burdens of proof of safety that would lead to more expensive products on the market. The consumers, however, are not sufficiently aware of the meaning of the CE Marking, which often leads to a perceived need for additional intervention of conformity assessment bodies.

11. It has been maintained that the CE Marking only targets Market Surveillance authorities. One should however bear in mind that it also targets the market. Hence, consumers making their choice of safe products in the market should be able to rely on it as proof of conformity with the regulated safety requirements.

12. There is a need to clarify and promote the meaning of the CE Marking for the consumers. It should not be an issue for the consumers which conformity assessment procedure has been used in the evaluation of the products if the legislators have agreed on the appropriate procedure on the basis of risk assessment.

13. It has been estimated that the costs of conforming to the requirements for CE Marking amount to one percent of the production-related cost. The costs for each additional mark have also been estimated to amount, on average, to one percent. Hence, the result would be higher prices to the consumer and diminished competitiveness for European companies.

14. Should voluntary quality marks alongside the CE Marking be deemed to add value, it should be ensured that these marks do not obscure the meaning of the CE Marking and that they reflect conformity with European standards. Increased efforts should be made to strengthen the Keymark as a single voluntary quality mark in Europe attesting conformity with European Standards. It must be ensured that the meaning of the Keymark is unambiguous, based on an open and transparent system. Furthermore, efforts should be made to create a European-wide framework for additional voluntary markings demanded by the market forces, such as other product or system quality characteristics than those specified in European Standards, environmental or other marking systems.

15. Studies have shown that consumers have the greatest confidence in quality marks operated by national organizations that are known to be impartial, e.g. national standardization organizations. These organizations are usually established and governed by national interest organizations and public authorities and enjoy public funding. It should be looked into whether support to nationally based voluntary

quality marks is consistent with the obligations of public authorities relating to the Internal Market. The EEA EFTA States have, supported by Sweden in the framework of the Internal Market Strategy, proposed a study on the organisation of the voluntary quality marks services in Europe as well as the sources for the demand for these.

1.3 Conformity assessment procedures

16. The EEA EFTA States recognise that a problem can arise from conflicting conformity assessment requirements stemming from different directives being applicable to one and the same product. The EEA EFTA States are, however, concerned that the proposed systematic recourse to Modules H, E or D could lead to de facto mandatory intervention by a notified body. Hence, third party intervention should only be appropriate in cases where specific safety concerns call for this.

17. A certain potential for improvement exists with regard to module H. In this context it should be ensured that the conformity assessment body responsible for the evaluation of the overall quality system of a manufacturer focuses on product specific aspects that have to be fulfilled.

18. Thus, every conformity assessment body in charge of an assessment according to module H must possess sufficient knowledge of the relevant product specific aspects for such an assessment. Therefore, the EEA EFTA States find that every new approach directive that refers to module H should contain explicit requirements concerning what knowledge of product specific aspects (in addition to Quality Systems related issues) conformity assessment bodies must have in order to be competent to perform the relevant evaluation procedures.

1.4 Notified bodies

19. The EEA EFTA States support the need expressed in the Communication to intensify the work towards homogeneous designation procedures for notified bodies in order to achieve the aim of credibility of the bodies. The requirements the notified bodies have to fulfil should be consolidated in close co-operation with groups of Member States' officials.

20. The EEA EFTA States support introducing into the New Approach Directives the obligation for notified bodies to participate in exchanges of experience and punitive action to be taken when a notified body fails to perform these duties.

21. The EEA EFTA States furthermore support the establishment of a forum for Member States’ officials responsible for the designation of notified bodies and accreditation bodies in order to facilitate the exchange of best practices for the assessment, designation and surveillance of notified bodies. This forum should develop a guidance to be followed, in the first instance, on a voluntary basis. Should this be insufficient, legal measures should be investigated.

22. Concerning the legal basis for accreditation, the EEA EFTA States find that no distinction should be made between the regulated and the non-regulated fields. Furthermore, accreditation should be seen as the apex of the quality infrastructure within the EEA and any further addition of a layer of conformity assessment activities should be avoided, as this would only add more costs without corresponding benefits to our economies. To this end a clear legal basis at Community level needs to be established for accreditation as a non-competitive activity.

23. There may also be advantages to developing a legal basis covering the situations when accreditation is not used as a basis for the designation of notified bodies. Use of different methods for assessing applicant notified bodies may be a greater risk to lack of harmonisation in the designation process than small differences when accreditation is used.

24. The EEA EFTA States recognise the problems related to cross-border activities of notified bodies and that a legal gap exists since designating authorities do not have the power to monitor the activities of notified bodies outside the state designating them. The EEA EFTA States support the establishment of a legal basis to deal with this, focussing on the conditions under which cross border activities should be allowed. Finally, the EEA EFTA States see Multilateral Agreements (MLAs) between accreditation bodies as a powerful vehicle to open up trade between the EEA area and states outside the area. The credibility established between conformity assessment bodies on the basis of these accreditation agreements can be seen as a powerful alternative to Mutual Recognition Agreements, which have been seen as notoriously heavy to manage. The EEA EFTA States therefore support the proposal for further efforts by the European Commission to establish a structured framework to allow conformity assessment bodies outside the EEA to perform tasks corresponding to the notified bodies activities within the EEA, paying special attention to the possible benefits of MLAs.

1.5 The Safeguard Clause in the New Approach Directives

25. According to the Communication, the safeguard clause procedure is currently time consuming, ineffective and is not applied equally throughout the EEA, e.g. in the sectors of medical devices and electromagnetic compatibility. The EEA EFTA States therefore give their support to the simplification of the procedure and to ensuring a uniform application of the procedure over the whole of the EEA area.

26. In relation to this, it should be underlined that the safeguard clause is the last resort. National authorities should be encouraged to participate actively in the development of standards relevant to their fields of activity and alert the European Commission in a timely fashion to concerns they might have as to the directions taken in the development of individual standards.

1.6 Outsourcing of the evaluation of applications of the safeguard clause

27. On the EEA EFTA side, it is the EFTA Surveillance Authority, which is currently responsible for the technical analysis relating to the application of safeguard

clauses, with the aim of establishing whether or not measures taken under the safeguard clause are justified. As stated above, the EEA EFTA States would, for all purposes, favour the simplification of the safeguard procedure. However, should it be decided to create a body to pool technical resources and expertise in the case of the evaluation of safeguard clauses and to take care of other logistical tasks, the access of the EFTA pillar to such a body has to be safeguarded. We understand that the body's competence would depend on its organisational structure and dependency. However, homogeneity in the application and approach of the EEA Agreement would call for a full (or equal) access for the EFTA pillar to such a body.

1.7 Relationship with the directive on General Product Safety

28. The EEA EFTA States agree with the proposal to introduce provisions for a rapid information exchange mechanism in the new approach directives. This would be an important instrument to make market surveillance more effective.

1.8 Common base directive

The EEA EFTA States agree that a common base directive, encompassing the common elements of the existing and future New Approach Directives seems to be an effective way of ensuring the homogeneity of the legislation and would also contribute to increased transparency of the legislation for market players.