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SUBCOMMITTE I ON THE FREE MOVEMENT OF GOODS

EEA EFTA COMMENTS ON COM (2007) 37: A PROPOSAL FOR A REGULATION SETTING OUT THE REQUIREMENTS FOR ACCREDITATION AND MARKET SURVEILLANCE RELATING TO THE MARKETING OF PRODUCTS, AND ON COM (2007) 53: A PROPOSAL FOR A DECISION ON A COMMON FRAMEWORK FOR THE MARKETING OF PRODUCTS.

These comments and proposals are made by Iceland, Liechtenstein and Norway (the EEA EFTA Member States) and are supported by Switzerland.

General comments

The EEA EFTA Member States recognise the New Approach as an important and successful 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 in ensuring that safe products are placed on the market. The CE marking system is widely recognised. This regulatory framework is complemented with important Old Approach legislation. Together they constitute an important part of the legal framework for goods in the Single Market.

However, we agree that this legal framework can be improved and streamlined, if appropriate, 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. Accreditation is the best tool in that respect. Market surveillance within the Internal Market and along its external borders needs to be improved. Strengthening the credibility of the CE marking is crucial. It must be recognised that the CE marking is no longer an instrument for manufacturers and market surveillance authorities only. It should also be recognised that the CE marking is relevant also to consumers, and its meaning should be clarified to them.

We therefore generally support the approach chosen by the European Commission in COM (2007) 37 and 53. Some improvements are however proposed.

As a general observation, we are of the opinion that, in the name of better regulation, all references to other acts, c.f. Article 1(2), should be accompanied by the full name of this act (at least the first time it is referenced).

Penalties (relate both to COM (2007) 53 and COM (2007)37).

With regard to Article 1(7) of (2007) 53, and Article 36 of (2007)37, it is important for the EEA EFTA Member States that the present wording "(…) penalties, which **may** include criminal sanctions**,** for serious infringements, (…)" (our emphasis) is kept.We suggest that the Danish and Swedish translations of the two proposals be improved, as they do not include the word "may".

The legislative approach – a Regulation and a Decision – CE marking

As to the choice of legislative approach, the European Commission has proposed one Regulation and one Decision, the latter having effect on new legislation and revision of existing legislation.

However, for the benefit of consumers, it is necessary to strengthen the legal protection of the CE marking at national level as soon as possible, and to introduce proportionate sanctions if the CE mark is unduly affixed. We would like to propose that it is reconsidered to move the provisions on CE marking from the Decision to the Regulation. Alternatively, if for technical reasons this should prove to be difficult, we would propose that at least Article 17(7) of (2007)53 be moved to a suitable place in the Regulation. Article 17(7) introduces new obligations addressed to Member States. We believe that this would not contradict any present obligations laid down by EU/EEA product legislation, as similar provisions are not included in other legislation. Reference is made to our comments on penalties above.

Within this context, we find it appropriate to add some additional comments and a proposal on CE marking, with reference to COM(2007)53.

CE marking means that the manufacturer declares that the product is in conformity with relevant EEA legislation and European standards. This meaning is not changed by the fact that different modules for conformity assessment have been applied for different products or aspects of the same product, e.g., whether third-party involvement is required. 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 should still be able to rely on a CE marked product being manufactured in accordance with EEA rules. However, we agree that there is room for improvement, hence COM(2007) 37 and 53, inter alia to reduce the risk of misuse of the CE marking. At the same time, it should be noted that the "simple" understanding of the CE marking is more complex with regards to CE marking on construction products.

Consumers should be better informed about the meaning of the CE marking. We think that the time has come to realise that the CE mark does not concern businesses and market surveillance authorities only (the intended use when it was introduced). CE marking also contains important information for consumers.

This view is supported in point 5.2 of the communication from the European Commission, COM(2007) 35, on the Internal Market for Goods,: "In theory, the role of the CE marking is simple: it shows to enforcement authorities and to **consumers** that the manufacturer declares that he has applied all applicable EC directives" (our emphasis). We propose that this be reflected in a Recital in the Decision, or in the Regulation if the provision on CE marking is moved.

Specific comments to COM (2007)37

The EEA EFTA Member States support the fact that food-law and feed- law are excluded from the scope of the proposal, c.f. Article 1(2) (a) and (b). For the sake of clarity, we propose that article 1.2 (a) should read "….as regards Chapter II **of this Regulation,**…".

The EEA EFTA Member States recognise the important role of the European co-operation for Accreditation (EA). We find it important that EA is recognised by the EU and EFTA. We furthermore acknowledge the importance of an efficient peer evaluation system among accreditation bodies. To further emphasize the important role of EA, we propose the following amendment to Article 4(8): "The national accreditation body **must be a member** of the European co-operation for Accreditation (EA)". This to ensure that, if the EA does not accept a national accreditation body, that body would have to make improvements and re-apply for membership.

The EEA EFTA Member States emphasize that all measures taken by the authorities must be in proportion with the degree of the product's lack of conformity.

We believe that a uniform market surveillance framework, with improved efficiency, is important for all products in the Single Market, independently of whether the products are regulated or not, or supplied as capital or consumer goods (or both). Article 13(2) states that Articles 14-23 (on market surveillance) shall not apply to products as defined in Article 2(a) of Directive 2001/95/EC (GPSD) in so far as the health or safety of consumers is concerned. We find it unclear what the impact of this exemption would be, and whether it is necessary.

Furthermore, if Directive 2001/95 lays down procedures for market surveillance and/or notification systems that are deemed more efficient than those laid down in the present proposal, we would propose that those mechanisms be clearly identified in consultation with the European Commission's services and incorporated into the present proposal, rather then being "excluded" by Article 13(2).

Articles 18, 24, 25 and 26 use the term "serious risk". In articles 17(2), 21 and 22 the term "risk" is used. We would propose a clarification as to whether these differences are intended and have been assessed, and if not, streamlining is needed.

Specific comments to COM (2007)53

The EEA EFTA Member States recognise the New Approach as an important regulatory tool in the Single Market. We support the New Approach being used as widely as possible. Nevertheless, we would like to underline that the New Approach may not be suitable for all product categories, e.g. some products constituting a

danger to health and/or environment. We are especially concerned about the recently adopted REACH Regulation, as well as regulations concerning cosmetics and GMO.

Therefore, we emphasise that it is important that, in the adopted version of the Decision, the following text in Recital 2 is maintained **: "***This Decision provides common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. This Decision therefore constitutes a general framework of a horizontal nature for future legislation harmonising the conditions for the marketing of products and a reference text for existing such legislation.* ***However, the specificities of sectoral needs may provide grounds for having recourse to other regulatory solutions*** (our emphasis)".

The EEA EFTA Member States support the exclusion of food-law and feed- law from the scope of the proposal, c.f. Article 1(1) (a) and (b).

In Article 3(1), the term "*too burdensome*" is used. This term is unclear and could lead to difficult questions of interpretation. We therefore propose the following amendment: "the need to impose modules which shall be **proportionate** to the risk".

Article 9(3) requires the importers to indicate their name and address on the product. This demand will inflict additional economic burdens on economic operators. We consider that these are not in proportion to the benefits gained by such a demand. We therefore propose that it should be sufficient for importers to state their name and address in the accompanying documents, which are included with the products. In this context, it is important for the consumer to know where they can find relevant information.

Article 9(5) and 10(4) places extensive burdens on importers/distributors, which include bringing the product in conformity with applicable Community legislation and taking necessary corrective measures to bring that product into conformity. We are of the view that the obligations "*to bring a product into conformity*" should pertain to the manufactures. The importers'/distributors' duty should be to inform the manufacturer about the problems or withdraw the product from the market. We therefore propose that Article 9(5) is amended to read: "*"…applicable Community legislation* ***shall immediately inform the manufacturer and ensure that the manufacturer takes*** *the necessary corrective measures to bring that product into conformity, or withdraw it from the market and recall it from end users, if appropriate."*

We also want to point to a possible contradiction between "making a product available on the market" in Article 10, and the definition of this term in Article 6. We interpret Article 6 as implying that when a product is made available for distribution, it is already "made available on the market".

In article 15 concerning EC declaration of conformity, there is a demand for the declaration to be "continuously updated". It should be clarified what is meant by "continuously". A better wording would be "updated, if appropriate".

We support the fact that accreditation is the best tool to assess and monitor the competences of conformity assessment bodies. We also support the fact that when

accreditation is not relied upon, or only partly relied upon, the body carrying out the assessment and the monitoring of a notified body should itself fulfil a set of conditions, c.f. Article 20. However, to avoid notifying authorities being subject unnecessarily to the conditions laid down in Article 20 when relying fully on accreditation for assessment and monitoring, we propose the following clarification to the introduction to Article 20: "*Requirements relating to notifying authorities that do not fully rely on accreditation for assessment and monitoring of conformity assessment bodies*"