Requirements for accreditation and market surveillance relating to the marketing of products (repeal. Regulation (EEC) No 339/93)

2007/0029(COD) - 27/11/2007

The Committee on the Internal Market and Consumer Protection adopted a report drafted by Andre **BRIE** (GUE/NGL, DE), amending, under the first reading of the codecision procedure, the proposal for a regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products.

The main amendments made in committee were as follows:

Objective: Members felt that the proposal offers an opportunity to establish a broader framework for both accreditation and market surveillance. An amended clause on the objective stipulates that, to ensure that products benefiting from the free movement of goods within the Community respect a high level of protection of public interests such as health and safety in general, health and safety at the workplace, protection of consumers and of the environment, while ensuring that the free movement of products is not restricted beyond what is allowed under Community harmonisation legislation, this Regulation provides a framework supporting specific rules of sectoral Community harmonisation legislation, without making any substantive changes to that legislation, in particular, without making changes to rules relating to protection of health and the environment and any specific rules on accreditation and market surveillance.. For these purposes, this Regulation lays down: a) rules on the organisation and operation of accreditation of conformity assessment bodies; b) a framework for market surveillance and for the control of products from third countries; c) provisions relating to the Community CE mark and CE marking.

Scope: favouring a broad scope of application the Committee removed all the exclusions proposed by the Commission. Instead, the general principle that more specific rules have precedence over more general rules is restated. Some definitions, such as “products”, “Community harmonisation legislation”, “entering the Community market”, “conformity assessment”, “CE marking”, “peer evaluation” and release for free circulation” have been introduced.

Accreditation and conformity assessment: the scope of the accreditation framework should be as wide as possible to prevent the creation of several parallel systems, but it should be clearly linked to the existing framework. The Committee stated that the Commission shall draw up and update the list of the national accreditation bodies operating in each Member State. That list shall be made publicly available by the Commission. The national accreditation body shall act as a public authority and in the public interest. It must not provide commercial consultancy services, own shares or otherwise have a financial or managerial interest in a conformity assessment body.

Members introduced a new Article on the principle of non-competition. National accreditation bodies shall not compete with conformity assessment bodies, or with other national accreditation bodies within the territory of the European Union with respect to accreditation for compulsory conformity assessment activities. National accreditation bodies shall, however, be permitted to operate across Member State borders, within the territory of another Member State, at the request of a conformity assessment body in respect of accreditation for a compulsory conformity assessment activity in certain circumstances.

National accreditation bodies shall establish and maintain appropriate structures to ensure the effective and balanced involvement of all interested parties both within their organisations and the European accreditation network.

It must be guaranteed that conformity assessments are carried out in an appropriate manner, meaning that unnecessary burdens are not imposed on undertakings and that due account is taken of the size of the undertaking, the sector in which it operates, the structure of the undertaking, the degree of complexity of the product technology in question and the mass nature of the production process.

Stakeholders shall have the right to participate in the system set up for the supervision of peer evaluation activities.

European accreditation infrastructure: the Committee inserted a clause stating that the Commission shall, after consultation with the Member States, recognise a body which satisfies the requirements of the Annex to the Regulation. In order for a body to be recognised, it shall conclude a framework agreement with the Commission. That agreement shall contain, inter alia, the detailed tasks of the body, breach of which will entitle the Commission to terminate the agreement, funding provisions and provisions for the supervision of the recognised body, as well as other provisions customary for an agreement of its type. The Commission and the body concerned shall make the framework agreement public. Both the Commission and the body concerned shall be able to terminate the agreement without cause at the expiry of a reasonable notice period to be defined in the agreement. The first body recognised under this Regulation shall be the European Co-operation for Accreditation, provided that it has concluded a framework agreement as aforesaid.

Market surveillance and customs authorities: contrary to the Commission proposal, the Committee felt that a framework for market surveillance should by its very nature be broad, and accordingly, it stated that Directive 2001/95/EC (the General Product Safety Directive) must be included in the market surveillance regulation. Similarly, the Committee did not approve of the exclusion of 15 pieces of other legislation under Article 13(3), as this would contradict the establishment of an efficient market surveillance based on EU-wide rules. It stated that the objective of market surveillance is to ensure that products covered by Community harmonisation legislation which, when used for their intended purpose or under conditions which can reasonably be foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in Community harmonisation legislation, are withdrawn, or restricted and that the public, the Commission and the other Member States are informed. Furthermore, Member States shall ensure that their market surveillance covers the full range of products which are subject to legal requirements, irrespective of whether they are intended for consumers or likely to be used by consumers, or intended for professional use.

Member States shall ensure that market surveillance programmes are established, implemented and periodically updated. Each Member State shall draw up a global market surveillance programme within one year of the date of entry into force of the Regulation and communicate it to the other Member States and the Commission and make it available to the public on the internet. Subsequent updates of that programme shall be made public in the same manner. Member States may establish co-operation agreements with stakeholders, in particular with sectoral professional organizations, in order to take advantage of available market intelligence.

The decision as to whether or not a product represents a serious risk shall be based on an appropriate risk assessment based on the character of the risk and the likelihood of it occurring. The Committee gives an outline of the nature of the risk assessment.

Control of products entering the Community market: Members felt that co-ordination and exchange of information between customs and market surveillance authorities had to be strengthened. Member States must ensure that their relevant authorities responsible for control of products entering the Community market have the necessary powers and resources in order to properly perform their tasks. Member States shall also ensure the effective cooperation between customs and market surveillance authorities. Where in a Member State more than one authority is responsible for market surveillance and customs controls, those authorities shall co-operate with each other.

CE marking: the Committee felt that the CE marking needed better protection and inserted a new clause entitled “General Principles of the CE Marking”. The provisions are (inspired by the proposed Decision. (Please see COD/2007/0030.)

Review clause: not later than 5 years after the entry into force of the Regulation, the Commission shall submit to the European Parliament and to the Council a report on the application of the Regulation and Directive 2001/95/EC on General Product Safety and any other relevant Community instrument addressing market surveillance. In particular, the report shall analyse the coherence of Community rules in the field of market surveillance. If appropriate, the report shall be accompanied by proposals to amend and /or consolidate the instruments concerned, in the interests of better regulation and simplification. The report shall include an evaluation of the extension of the scope of Chapter III of the Regulation to all products.