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

2007/0029(COD) - 21/02/2008 - Text adopted by Parliament, 1st reading/single reading

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

The main amendments were as follows:

Objective: Parliament made some amendments to this Article which now states that the Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities. It also provides a framework for the market surveillance of transformed products to ensure that they respect a high level of protection of public interests such as health and safety in general, of health and safety at the workplace, protection of consumers, of the environment, and of security. The Regulation further provides a framework for controls on products from third countries. It also contains provisions on **CE marking**.

Accreditation and conformity assessment: each Member State must appoint a single national accreditation body. The Commission shall draw up a list of the national accreditation bodies, to be made publicly available. Where accreditation is not operated directly by the public authorities themselves, Member States shall entrust the national accreditation body with the operation of accreditation as a public authority and grant it formal recognition on behalf of the government. The national accreditation body must not provide any services that conformity assessment bodies provide, nor shall it provide consultancy services, own shares in or otherwise have a financial or managerial interest in a conformity assessment body. Each Member State shall ensure that its national accreditation body has the appropriate resources for the proper performance of its tasks including for the fulfilment of special tasks, such as activities in European and international accreditation cooperation and activities that are required to support government policy and which are not self-financing. The national accreditation body shall be a member of the body recognised by the Commission as managing the European accreditation infrastructure. National accreditation bodies must maintain appropriate structures to ensure the balanced involvement of all interested parties. Member States must monitor their national accreditation bodies and take the utmost account of the results of peer evaluation. Stakeholders shall have the right to participate in the system set up for the supervision of peer evaluation activities, but not in individual peer evaluation.

Principle of non-competition: a new Article on the principle of non-competition states that 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.

Parliament added that a national accreditation body shall verify 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.

European accreditation infrastructure: Parliament 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 an agreement with the Commission. That agreement shall contain the detailed tasks of the body, funding provisions and provisions for the supervision of the recognised body. The first body recognised under the Regulation will be the European Co-operation for Accreditation.

Market surveillance: provisions on market surveillance will apply in so far as there are no specific provisions with the same objective in rules of Community harmonisation legislation. The application of the Regulation will not prevent market surveillance authorities from taking more specific measures as provided for in Directive 2001/95/EC (GPSD).Market surveillance shall 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, prohibited or restricted from being made available on the market and that the public, the Commission and the other Member States are appropriately informed. National market surveillance infrastructures shall ensure that effective measures can be taken in relation to any product category subject to Community harmonisation legislation. Such surveillance shall cover products assembled or manufactured for the manufacturer's own use where Community harmonisation legislation provides that its provisions shall apply to such products.

Parliament went on to specify that Member States shall draw up either a general market surveillance programme or sector specific programmes, covering the sectors in which they conduct market surveillance, communicate those programmes to the other Member States and the Commission and make them available to the public, including by ways of electronic communications. The first such communication shall take place by 1 January 2010. Member States shall periodically review the functioning of their surveillance activities. Such reviews and assessments shall occur at least every fourth year and the results shall be communicated to the other Member States and the Commission and made available to the public.

On the question of risk, Parliament stated that 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 hazard and the likelihood of it occurring. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to present a serious risk.

Control of products entering the Community market: 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. 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: Parliament inserted a new clause entitled “General Principles of the CE Marking”. The provisions are inspired by the proposed Decision. (Please see COD/2007/0030). The CE marking shall only be affixed by the manufacturer or his authorised representative.

Review clause: not later than 5 years after the entry into force of the Regulation, the Commission shall submit 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. It will include an evaluation of the extension of the scope of Chapter III to all products.