



ORGALIME

Clear and Common Definitions for EU product legislation *in the context of the review of the New Approach*

ORGALIME POSITION

9/10/2005

Orgalime's 35 trade federations in 24 countries represent some 130,000 companies in the mechanical engineering, electrical, electronic and metalworking industries. The industry employs some 7 million people and includes a substantial majority of small and medium-sized companies, which generate 1,235 billion euro of turnover per year and account for over a quarter of the production and a third of the industrial exports of the European Union.

In this position paper we comment on to a few key definitions as described in the EC working document "Draft Certif Doc. 2004-1", dated 26 October 2004. In a separate position paper "towards comprehensive and efficient market surveillance", Orgalime stresses the need to review the liability of market operators in EU product directives in an equitable and pragmatic manner, according to their functional responsibility on the market. The key definitions on which we comment in the present position paper are essential for this purpose.

Clear definitions in support to better enforcement and confidence

All stakeholders have an interest in ensuring that products sold on the Internal Market comply fully with the essential requirements of the appropriate legislation. The principles of the New Approach are based on confidence: confidence that manufacturers are only placing compliant products on the market and confidence that authorities fulfil their task of ensuring efficient market surveillance.

To ensure the enforceability of legislation there must be a clear and unambiguous understanding of what triggers liability of the various market operators according to their function on the market and how these operators relate to the product during its whole lifetime (design, manufacturing, import, distribution, installation, use, maintenance and disposal).

The specific functions of each market operator should, in our view, be assessed and defined accordingly in each product directive.

Common definitions for consistent and facilitated compliance

When discussing general definitions one should take into account that any product is more and more subject to a range of different directives which each have their own scope and obligations, for example: environmental conscious design - product safety - product liability - waste disposal - proof of conformity - contact point for the authorities - reporting of unsafe products ...

Over the years, different definitions have been used to address the same concepts in different product legislation. This is causing confusion for stakeholders, especially when different directives apply to the same product. Consequently Orgalime suggests that common definitions should be adopted according to the suggestions in the present paper for all New Approach and other EU product directives, in order to provide more consistency in the regulatory framework and to facilitate the application and enforcement of such directives. We provide hereafter our proposals for such key definitions.

"MANUFACTURER"

- means the natural or legal person who is responsible for the design and/or manufacture of a product with a view to its being placed on the Community market and/or put into service under his own name or trademark.

A manufacturer may have the product designed, manufactured, assembled, packed, processed or labelled in part or wholly by somebody else. He must, however, retain the overall control for the product.

Note:

The draft Certif doc. 2004-1 includes in the proposed definition of a manufacturer the putting on the market of a product *for its own use*. It should be stressed that the manufacturing of a product for own use should not be considered as *placing the product on the market*. We understand that this issue is presently under examination by the legal services of the EU Commission.

Orgalime is of the opinion that as a general rule the manufacturing of a product for own use should not be regarded as "placing on the market" and therefore the obligations put on manufacturers should not be applicable in these cases. Exceptions may be found in specific directives, such as the machinery directive, when duly justified.

"AUTHORISED REPRESENTATIVE"

- means any natural or legal person established within the Community who has received a written mandate from the manufacturer to act on his behalf for specific tasks with regard to the latter's responsibilities under the Directive.

Note:

It can be questioned whether it is appropriate to maintain the notion of an authorised representative. However, the appointment of an authorised representative may become more important in future as distance shopping increases (e.g. internet sales shipped by mail).

"EU-IMPORTER"

- means any natural or legal person established in the Community who places a product from a third country on the Community market.

Note:

It is considered appropriate to operate with the notion of EU-importer to distinguish between importing directly from a third country from importing from one EU to another EU member state in the internal market.

When the manufacturer is not established within the Community and in the absence of an authorised representative, the EU-importer must assume the responsibilities placed on the manufacturer regarding the conformity of the product to the essential requirements, e.g. regarding proof of the conformity of the product to the essential requirements of EU directives. The EU-importer should bear the responsibility, to make the necessary verification that the product is indeed intended to be placed on the internal market and manufactured for the EU market according to our regulations. The character of his obligation must be specified in the directive in question.

"PLACING ON THE MARKET"

- means the initial action of making a product available for the first time on the Community market, with a view to distribution or use in the Community, whether in return of payment or free of charge.

Note:

The draft Certif doc. 2004-1 defines *placing on the market* as making available *for end use*. It should be noted that in the Low Voltage Directive (73/23/EEC) all electrical equipment (with only a few exemptions) is included in the directive. This means that products intended to be incorporated into other equipment are also subject to the provisions of the directive.

With a general definition linking *placing on the market* with *end use*, a manufacturer could declare a product as "*not* being intended for end use" and thus open a way to avoiding his obligations to fulfil the requirements of the directive.

This is why Orgalime suggests leaving out the wording "intended for end use" in the horizontal definition of "placing on the market".

We suggest that end-use and end-users are defined in specific directives, when needed.

THE USE OF THE TERM "PRODUCER" SHOULD BE AVOIDED

Orgalime believes that the term of producer, which is used in some product directives, is a source of confusion for the following reasons:

- In some directives the term "producer" covers several functional responsibilities of market players: e.g. in the WEEE and ROHS directives, the term producer is defined as "*any natural or legal person established within the Community who, irrespective of the selling technique used, places a product on the Community market*". This means that a producer can be the manufacturer, the importer, and/or the distributor. Consequently, one product may have several "producers", which makes it difficult to assess the nature and extent of responsibilities for each of them. This may lead to misunderstandings and provides no added value for market surveillance purposes;
- The term "producer" gives rise to terminological problems from one to another EU country: e.g. in the German version of the WEEE or the RoHS directives, the term "producer" is translated by "Hersteller" (and not by "Produzent"). Unfortunately, "Hersteller" (DE), is commonly used in New Approach directives, the Product Liability directive and the General Product Safety Directive, where it is the translation of "manufacturer" (EN) or "constructeur" or even "fabricant" (FR) with a more specific meaning. Consequently, in the German versions of the various directives, the term "producer" could be misleading.

Orgalime consequently suggests that the term *producer* should *not* be a used in future product directives.

Definitions on other concepts may be needed in order to solve specific concerns in specific directives.

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