NLF interpretative Fiche

Orgalime Position Paper

Title Short:

Translation requirements

Fiche Nb:

3

Subject:

Translation of the Declaration of Conformity (DoC) and of the technical documentation (TD) into a language "easily understood" by market surveillance authorities.

Last Update:

18-03-2011

Category:

Obligations for economic operators

Legal basis:

Decision, art. R2.9, R4.9, R.34.1(e)

Legislative references:

- **Regulation** No 765/2008/EC of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation No 339/93/EEC – Published in the OJEU L 218/30 of 13/08/2008
- **Decision No 768/2008/EC** of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC – Published in the OJEU L 218/82 of 13/08/2008

ISSUE TO BE ADDRESSED:

According to Articles R2.9 and R4.9 of Decision No 768/2008/EC, manufacturers and importers *"shall, further to a **reasoned request** from a **competent national authority**, provide it with all the information and **documentation** necessary to demonstrate the conformity of the product, in a **language which can be easily understood** by that authority. They shall cooperate with that authority, at the request of the latter, on any action to avoid the risks posed by products which they have placed on the market".*

Translation into different languages of the whole technical file, which can contain several hundreds of pages, would generate significant administrative burdens and costs for manufacturers, especially SMEs, without clear added value for the authorities concerned.

The following points should be clarified:
1) The definition of what is meant by a "reasoned request".
2) How should the communication between the "competent national authority" and the manufacturer be organised?

SOLUTIONS PROPOSED BY ORGALIME:

It should be clarified that

1) A "*reasoned request*" usually means that the authority should define the proven or claimed non-conformity. Therefore, it should be sufficient to send only **the part of the technical file** related to the claimed non-conformity and appropriate for demonstrating whether the issue has been dealt with. The request for translation of the technical documentation should thus be strictly limited to those parts of the documentation which are relevant to assess the claimed non-conformity or to demonstrate whether the non-conformity has been addressed.

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2) Translation into "*a language which can be easily understood*" by the competent national authority is meant to indicate that the manufacturer does not have to translate the technical file necessarily into the national language of the relevant authority, but that the language chosen is subject to negotiation with the authority and could be a third language, such as English.

3) The "*competent national authority*" means the relevant market surveillance authority of the Member State **where the manufacturer or the importer is established**. Considering the obligation for cooperation set out in Article 24 of Regulation 765/2008, this authority should be given the lead in dealing with a specific case of non-compliance vis-à-vis the manufacturer or importer.

National authorities should make full use of cooperation and coordination between all EU market surveillance authorities as set out in Articles 24 to 26 of the Regulation 765/2008/EC. Wherever possible, a national authority which claims non-conformity should first contact the relevant market surveillance authority of the country in which the manufacturer or the importer is established and ask it to cooperate in the further investigation and handling of the case, such as requesting the technical documentation from the manufacturer in the national authority's language.