ORGALIME
The Secretary General

Mr. Jacques McMillan
EUROPEAN COMMISSION
Head of Unit C/1
DG Enterprise and Industry
Rue de la Loi 200
B-1049 Bruxelles

14 April 2005

Re: Your letter ENTR/C1/GA/ah D(2005)4553 dated 24/02/2005
Review of the New Approach - ORGALIME views on conformity assessment modules

Dear Mr. McMillan,

In answer to your above mentioned letter, we are pleased to send you enclosed ORGALIME views on the conformity assessment procedures applying to New Approach directives.

ORGALIME believes that the conformity assessment modules generally are efficient for their intended purpose and give rise to few significant problems. We would wish to see continue the present arrangements whereby the selection of the applicable module depends on the risk related to the product. In particular, we urge regulators to continue to make use of Module A as the default choice in any new or revised product legislation. Indeed we believe the role of module A should be strengthened.

ORGALIME observes that the modules work quite adequately in practice. Problems arising with unsafe products are caused by the lack of effective market surveillance. The problem of dangerous products coming into Europe is not related to the modules, as past surveys have shown. Only market surveillance can cope with this problem.

ORGALIME would reject any suggestion that Module A needs additional requirements in order to have credibility. On the contrary, its record is very good and this is borne out by international comparisons between the EU and, for example, the USA. The level of safety in the EU in this field has increased through the responsible actions of manufacturers in developing a very sound corpus of harmonized standards for products to follow. We believe it has to be accepted that for some critics of industry nothing less than full third party verification of every parameter will ever be adequate; so they are unlikely to be satisfied by any added requirements to module A which fall short of that.

ORGALIME also firmly believes that replacing Module A with module H as the default choice would cause unjustified burdens to our industry, not least to SMEs; we continue to support the principle that the least onerous procedure (module) consistent with safety (or other risk being targeted) should be chosen by the regulators. Conformity assessment required by directives should continue to be the minimum required to fulfil the legislation and the product be considered “legal”, denoted by the CE marking accordingly. Steps over and above this legal minimum, in a competitive Europe should be a matter for the market.

Therefore ORGALIME believes that the modules should only be revised where there is a technical reason, as is the case with the modules citing ISO EN 9001, which was revised in 2000. We support the solution as practised today and described in the European foreword to EN/ISO 9001:2000, tailoring this standard to the requirements of the modules. By this means, one can be avoided the European legislator and industry having to be dependent on future revisions of ISO 9001 (the next round of which has already been started this year).

We are aware of very few cases where a directive gives manufacturers a choice between two modules, deemed equivalent but significantly differing in their procedures; most usually a directive offers one module as the baseline legal requirement and manufacturers do not have a choice. Of course there should be coherent and coordinated conformity assessment between directives, as is now the case between the LVD and EMCD for example, particularly now that environmental directives are also addressing themselves directly to product aspects. However, no particular problems are caused to manufacturers by having to fulfil two modules for two different product aspects, provided they do not actually conflict. Both have to be observed; they are not alternatives between which a manufacturer has to choose which better addresses both of the directives' requirements, so while there may well be scope for reducing the different number of modules available, in total, for the regulators to select from – there do seem to be rather a lot of third party variants – the two things should not be mixed up.

We do believe that the legislators in the area of the environment now bringing forward product measures impacting on the functioning of the internal market must become more familiar with the internal market's "new approach" principles, if the one is not to impede the other in the future. And all regulators should subscribe to the modules menu and avoid creating new variants in future.

In summary, ORGALIME sees few problems in the modules to justify significant changes being made, only some minor updating.

In order to adapt the modules to current practice, in addition to taking account of the revision of ISOO 9001, ORGALIME also proposes a slight amendment to module B in accordance with Directive 2004/22/EC Measuring instruments, where type testing may also be conducted in the form of evaluation of design documentation. Such an amendment would be very advantageous for highly innovative and expensive instruments.

In the interests of rationalising the modules requiring the involvement of a third party, we present our proposal in graphical form in Annex.

We hope that the Commission will duly consider our comments that we believe could help the Commission to make a success of the revision of the New Approach to technical harmonisation and of the Global Approach to conformity assessment.

Yours sincerely,

Adrian Harris
Secretary General
[Copy sent by electronic means.
Original with signature sent by post]

Cc: Messrs. Norbert Anselmann, Martin Stadler, Gero Leibrock. Mrs Rita L'Abbate.

ANNEX to ORGALIME views on conformity assessment modules