



**EUROPEAN COMMISSION**  
 ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Chemicals, metals, mechanical, electrical and construction industries; Raw materials  
**Mechanical, Electrical and Telecom Equipment**

Brussels,

**Subject: Lifejackets / buoyancy aids**

**Background**

The European Commission has been recently addressed with a number of inquiries regarding the new EN ISO 12402 series of standards superseding the EN 393, 4 ... series<sup>1</sup> concerning lifejackets and other buoyancy aids. The main issue at hand is that manufacturers are reluctant to use the new series of standards and hence do not benefit from the presumption of conformity that such standards provide.

Given that there are products on the market both manufactured according to the EN 393, 4 ...series of standards as well as the new EN ISO 12402 series, this reportedly causes disturbance on the European market and concerns for the relevant market surveillance authorities.

The responsible Commission Service undertook an inquiry in order to find out why this was happening to seek clarification from relevant experts regarding technical changes that the new EN ISO standards represent.

**Opinion of the European Boating Industry**

At the PPE Working Group meeting held on 29 April 2010, a representative of the European Boating Industry explained to the relevant stakeholders that:

1. In their opinion, there was no evidence that the lifejackets manufactured according to the old standards no longer complied with the relevant Basic Health and Safety Requirements (BHSR) of Directive 89/686/EEC (the PPE Directive);
2. The application of the EN ISO12402 series represented a problem for the (European) boating industry as it led to a more expensive conformity assessment procedure, placing a significant economic burden on the European manufacturers and weakening their competitive position vis-à-vis their competitors in third countries;

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<sup>1</sup> The standards EN ISO 12402 Parts 2,3,&4 were published in December 2006 and standards 393 ~ 399 ceased to give presumption of conformity as of March 2007.

3. Part 7 EN ISO 12402 (Materials and Components), which was a critical element for manufacturers in the decision to shift to the new standards, was not yet available.<sup>2</sup>
4. The European Boating Industry was of the opinion therefore that for new models of lifejacket, manufacturers should use the new standards, but for those already in production they would continue to apply the EN 393, 4 ... series.

### **Consultation of stakeholders**

During the above PPE WG meeting, stakeholders also highlighted that the new EN ISO 12402 series was under revision in order to better reflect the needs of the sector, without jeopardizing the health and safety of the users of lifejackets.

The responsible Commission Service also contacted the following stakeholders to verify the situation:

- The Convenor of Vertical Group 8 of Notified Bodies;
- The Federation of the European Sporting goods Industry (FESI);
- European Safety Federation (ESF);
- Working Group 6 of CEN/TC 162.

### **Outcome of inquiry**

The replies received confirm that the new EN ISO 12402 series includes more stringent testing specifications compared to the EN 393, 4 ... series, in particular, enhanced in-water tests and strength tests. CEN/TC 162 added that the new EN ISO 12402 series presented the relevant specifications in a more structured way.

However, to date, the responsible Commission Service has not been notified by any of the stakeholders that lifejackets manufactured according to the EN 393, 4... series of standards do not comply any more with the relevant BHSR of the PPE Directive or are unsafe to use.

In this respect, the recourse to enhanced tests does not in itself mean that products tested according to the previous version of a standard do not satisfy the BHSR of the PPE Directive. This can only be evaluated on a case by case basis.

It should be added that the fact that application of a standard costs more is not a valid reason for deferring its use if technical evidence shows that the health and safety of users is at stake.

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<sup>2</sup> Standard EN ISO 12402-7:2006 *Personal flotation devices - Part 7: Materials and components - Safety requirements and test methods (ISO 12402-7:2006)* was published by CEN on 28 February 2007 but its reference has not yet been sent for publication in the OJEU

## **Opinion of the responsible Commission Service**

The availability of a revised standard does not entail that a product designed to the previous version of the standard can no longer be considered to comply with the BHSR and can no longer be placed on the market.

This is only the case if:

- the revised standard remedies a deficiency in the previous version of the standard (for example, a deficiency established by a formal objection);
- the revised standard marks a significant improvement in the level of protection that can be attained. In such a case, products designed to the superseded version of the standard can no longer be considered as reaching the "highest level of protection possible" required by section 1.1.2.1 of Annex II to the PPE Directive.

In the cases outlined above, the Notified Bodies have the duty to withdraw EC type-examination certificates issued on the basis of superseded versions of harmonised standards, since the products concerned can no longer be considered to comply with the BHSRs of the PPE Directive.

In other cases, manufacturers may continue to place on the market PPE designed according to the superseded version of a harmonised standard. However, for new models of PPE, only application of the new version of the standard confers a presumption of conformity with the BHSRs of the Directive.

Where a manufacturer has not applied, or has only partially applied a harmonised standard, and thus does not benefit from a presumption of conformity, the adequacy of the measures taken in order to comply with the BHSR of the PPE Directive must be documented in the manufacturer's technical file and the Notified Bodies must check that the specifications used comply with the applicable BHSR and carry out the necessary examinations and tests.

The responsible Commission Service recalls the importance of harmonised standards and encourages manufacturers to apply such standards, both in order to benefit from the presumption of conformity and in order to achieve a high level of protection. Lifejackets placed on the market must be designed to provide the highest level of protection possible referred to in section 1.1.2.1 of Annex II to the PPE Directive. This implies keeping up with technical developments, including the improvement of the harmonised standards. The Commission therefore welcomes the commitment made by the representatives of the industry to apply the new harmonised standards of the EN ISO 12402 series for new models of lifejackets and trusts that the current revision of the EN ISO 12402 series will facilitate such application.

No evidence has so far been produced that would show that the new standard for lifejackets remedies a deficiency in the previous version of the standard or represents a significant improvement in the level of protection that can be attained. Consequently, unless technical evidence is notified to the responsible Commission Service to the contrary, the responsible Commission Service considers that lifejackets manufactured according to the EN 393, 4 ... series of standards subject to valid EC type-examination certificates issued before the cessation of presumption of conformity conferred by those

standards expired, continue to comply with the BHSRs of the PPE Directive. EC type-examinations carried out after the cessation of presumption of conformity of the EN 393, 4, ... series shall be carried on the basis of the new version of the standard or equivalent technical specifications.

The responsible Commission Service recognizes that Member States are responsible for market surveillance on their territory in order to make sure that only compliant products are placed on the European market. (Article 2 of the PPE Directive.) However the responsible Commission Service recalls that any restrictive measure taken by the Member States' market surveillance authorities against a CE marked product must be notified to the Commission in the framework of Article 7 of the PPE Directive, setting out the reasons for the measure. In this respect, the application of a superseded version of a harmonised standard is not, in itself, evidence of non-conformity.

The European Commission will continue to monitor this situation in order to make sure that the principles of the Treaty on the Functioning of the European Union and the provisions of the PPE Directive are fully complied with by all stakeholders.