OPINIONS

# EUROPEAN COMMISSION

## COMMISSION OPINION

**of 6 November 2012**

**on interim measures taken by the government of Germany in respect of life jacket lights of model Asteria manufactured by Sic Divisione Elettronica S.r.l. in the Republic of Italy**

**(Text with EEA relevance)**

(2012/C 339/02)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 96/98/EC of 20 December 1996 on Marine Equipment [1], and in particular Article 13 thereof,

Whereas:

(1) In accordance with Annex A.1 to the above mentioned directive, the applicable performance and construction requirements for life jacket lights are laid down in Resolution MSC.48(66) (LSA Code) of the International Maritime Organization (IMO) and the applicable testing standards for the said equipment are laid down in Resolution MSC.81(70) of the IMO.

(2) By letter of 10 March 2011 the German Federal Maritime and Hydrographic Agency, hereinafter 'BSH', informed the Commission of interim measures taken by this authority in respect of life jacket lights of model Asteria (hereinafter, 'the life jacket lights') manufactured by Sic Divisione Elettronica S.r.l. in the Republic of Italy (hereinafter, 'the manufacturer'), whereby the said life jacket lights belonging to the batch No 32210805 as well as all lights placed on the market since July 2009 were recalled from the German market on grounds of failure to comply with Article 5(1) of Directive 96/98/EC.

(3) The letter was accompanied by a detailed market surveillance report dated 2 March 2011 and a copy of each of the following documents: (a) the EC Type Examination Certificate (module B) for the life jacket lights, No MED094008CS/002, issued on 3 March 2008 by the notified body RINA and valid until 2 March 2013; (b) the Quality Assurance Certificate (Module D) for the life jacket lights, No MED068209TA/005, issued on 6 November 2009 by the notified body RINA and valid until 5 November 2012; (c) the Quality Assurance Certificate (Module D) for the life jacket lights, MED068209TA/003A, issued on 3 March 2008 by the notified body RINA and valid until 20 October 2009; and (d) a declaration of conformity of the life jacket lights for batch 32210805, issued on 13 July 2010.

(4) The interim measures followed after it was found that (a) the life jacket lights of batch 32210805 did not meet the above mentioned applicable requirements during tests that were carried out by BSH within the framework of a market surveillance program; (b) the bulb of the life jacket lights had been replaced from July 2009, without further approval; and (c) further tests on four specimens from batch No 15202001, which were delivered to BSH on 6 July 2010, had shown that also these specimens did not meet the applicable requirements as regards luminous intensity. More precisely, BSH reported that two specimens from batch No 32210805 had been tested to verify compliance with the requirements provided in the above mentioned Resolution MSC.48(66), section 2.2.3.1.1, whereby each life jacket light shall have a luminous intensity of not less than 0,75 candela (cd) in all directions of the upper hemisphere. The tests showed that, when measured at ambient temperature, the light output of one of the specimens did not reach the required intensity in the range of 0° to 25°, while the second specimen did not reach the required minimum level in the range of 0° to 10° and only partially in the range of 10° to 35°. The tests that had been carried out on the four specimens taken from batch No 15202001 showed that (a) when measured at ambient temperature, the light output of the first specimen only partially reached the requirements in the range of 0° to 20°, while the second specimen reached the requirements; and (b) when measured at – 1 °C, the third and fourth specimen only partially reached the requirements in the range of 0° to 30°. As regards the replacement of the bulb, BSH considered that

[1] OJ L 46, 17.2.1997, p. 25.

this should have been regarded as a modification of the approved product requiring additional approval where such changes could have affected compliance with the requirements or the prescribed conditions for the use of the product. BSH noted that the notified body RINA should therefore have been informed, which had not been the case.

(5) Upon receipt of the letter from BSH the Commission entered into consultation with the manufacturer, the government of Italy as the notifying Member State and the above mentioned notified body having issued the type-examination certificates in question on the latter's behalf (hereinafter referred to collectively as 'the parties'). The Commission asked a number of specific questions from each party and invited them to submit any other observations they might deem appropriate.

(6) In response to the Commission's consultation, the manufacturer submitted that: (a) the withdrawal of the life jacket lights had not been done for safety reasons, but for image reasons and that they would consider the actions from BSH unfair, (b) the bulbs they had been using had all been tested and approved in their certified laboratory and the change had not created any significant variation about the functionality of the lights, (c) they did not contest the tests performed by BSH; (d) the life jacket lights would not be a danger to health and/or safety of crews or passengers since the luminous intensity of the said life jacket lights was on average more than 0,75 cd and the points where a lower luminous intensity had been found would be mediated by those with intensity greater than this value, which would be correct since persons in the sea are in motion and not motionless; and (e) this concept of average values would be applied by many manufacturers.

(7) In its answer to the Commission RINA replied that (a) the module B certificate No MED81802CS had been issued by RINA on 7 March 2003 and, after a declaration was received from the manufacturer that no modifications had been made to the approved equipment, this certificate had been renewed and superseded by module B certificate No MED094008CS/002; (b) this certificate had in turn been withdrawn on 14 April 2011 at the manufacturers' request, since the life jacket light model Asteria had been replaced by model Asteria LED for which another certificate had been issued the same day; (c) they had not challenged the results of the tests performed by BSH; (d) following the information from BSH the Italian government in cooperation with RINA had undertaken an investigation in order to establish proper actions; (e) if lights were to be found defective, they should be withdrawn from the market; and (f) they would be able to define their final opinion after having considered the actions taken by the Italian Administration.

(8) Upon the Commission's request the Italian Administration replied that (a) they would in principle agree that non-compliance of the product with the requirements would not be acceptable; (b) as a preliminary understanding and position they would accept, in principle, the results of the tests performed by BSH; (c) they would consider a request to withdraw the identified batches from the European market as appropriate; and (d) they would inform the Commission of their final understanding and related decision once all documentation would be gathered.

(9) The Italian Administration in the same reply also stated that they had held a meeting with the manufacturer and the notified body where the former had stated that the change of the bulb did not have a significant impact on the luminous intensity of the light, and insisted on the arguments already given to the Commission and listed in recital 6 above. In that meeting an action plan had been agreed according to which (a) a technical assessment of the change of the bulb would take place; (b) non-compliant batches other than batch No 32210805 would be sought and identified; (c) evidence of actions to withdraw the identified defective batches would be provided; and (d) the production of the life jacket lights would be stopped. The Commission noted that no precise information was provided as to who would be responsible for the implementation of this action plan or whether production of the lifejacket lights would effectively cease or merely be suspended pending the outcome of the said action plan.

(10) The Commission asked BSH for their views on the observations received. In their answer BSH stated that: (a) it was not correct that all life jacket lights had the same problem to obtain the luminous intensity of 75 cd, as specimens of four other models had succeeded the tests; (b) it was not relevant that the luminous intensity requirement was met only on average, as some of the applicable requirements were not met; (c) the manufacturer had not indicated the exact date of the replacement of the bulb, despite BSH's repeated requests for information to the manufacturer; (d) RINA had confirmed that they had not been informed on the replacement of the bulb; (e) after this change, fulfilment of the requirements of the testing standard should have been checked again by the notified body; (f) the test results showed that, even after the replacement of the bulb, the minimum requirements on luminous intensity were still not met. BSH concluded that observations submitted by the manufacturer and the notified body did not warrant changes to the initial assessment and the reasons for the recall of the product remained, in BSH's view, valid.

(11) In a second communication to the Commission, the Italian Administration submitted a test report which was provided to them by the manufacturer and which contained the results of further tests carried out with specimens of life jacket lights type Asteria by the Laboratory of Photometry and Illumination Engineering of the National Centre for Research in Firenze. According to the Italian Administration the results showed significantly greater luminous intensity than the minimum required of 0,75 cd, without however achieving the mandatory coverage. Accordingly, the Italian Administration confirmed the accuracy of the findings of BSH and would not raise any objection if the product were to be recalled from the European market.

(12) BSH acted within the framework of a market surveillance program on life jacket lights, in accordance with Article 12 of Directive 96/98/EC.

(13) The manufacturer was informed of the results of the above mentioned tests and was given by BSH the possibility to present its observations and defend itself before the said Authority adopted any measures in respect of the product in question. Similarly, the notified body was informed and was given by BSH the possibility to present its observations.

(14) Nothing in the information and evidence available to the Commission warrants calling into question the tests carried out by BSH, which were not contested by the parties. On the contrary, the tests subsequently carried out by the Italian authorities confirmed the results of the former.

(15) Both the Italian authorities and the notified body agreed that the action taken by the German authorities, namely recall of the life jacket lights from the mentioned batches from the German market, was appropriate. Furthermore the Italian authorities agreed on the appropriateness of a broader recall.

(16) Paragraph 6 in the first section of Annex B to Directive 96/98/EC (EC type-examination — Module B) requires the manufacturer to inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved product, which must receive additional approval where such changes may affect compliance with the requirements or the prescribed conditions for use of the product. When a part of the product is replaced, this can only be considered a modification of the product when the replacement part specifications do not tally with the exact description of the replaced part in the technical documentation used for type-examination. Only in this case, or if in doubt, does the manufacturer's duty to inform the notified body arise.

(17) In the case under examination, the following technical particulars with respect to the bulbs of the life jacket lights have been provided to the Commission: (a) in the technical documentation concerning the EC type approval certificate the bulbs were described as 4 volts, 300 milliamperes; (b) the bulbs of the specimens taken from batch No 32210805 had been manufactured by Philips and were marked with '4,8V 300mA' (i.e. 4,8 Volts, 300 milliamperes); (c) the manufacturer of the bulbs taken from batch No 15202001 was Walter Schrickel GmbH (as was reported by the manufacturer to BSH) and the bulbs were marked with '4VO3W' (i.e. 4 volts, 3 watts which corresponds to 750 milliamperes). From this information it must be concluded that neither the bulbs which had been fitted in the life jacket lights taken from batch No 32210805 nor the bulbs which had been fitted in the life jacket lights taken from batch No 15202001 actually met the specifications of the approved type, and that this might affect the performance of the lights. It must also be noted that the manufacturer never disclosed this fact to the notified body. According to the information provided by the manufacturer to BSH, the replacement bulb, had been used for the first time in batch 32210805, which had been delivered to BSH on 27 July 2009. However, BSH had found that the bulb of the specimens of the life jacket lights taken from that batch, had been manufactured by Philips. Therefore it is reasonable to assume that the replacement of the bulb must have taken place at an unknown point in time during the production of batch No 32210805 and no earlier than July 2009.

(18) In accordance with paragraph 6 of the section 'EC type-examination (module B)' of Annex B to the above mentioned Directive, the manufacturer should therefore have informed the notified body with a view to obtaining a new approval of the lifejacket lights where a bulb not meeting the specifications of the original type were to be fitted. The manufacturer's argument that the changed bulbs they were using had been tested and approved in their certified laboratory cannot be upheld, as this is not a notified body duly notified to carry out conformity assessment procedures under the Directive, and the said testing did therefore not result in the issue of a new type approval certificate.

(19) As regards the performance of the tested lights, the manufacturer's argument that the average luminous intensity was more than 0,75 cd, that the light source moved in the water and that therefore the average luminous intensity could be taken as a satisfactory result cannot be upheld, either. The above mentioned performance requirements specifically provide that the required luminous intensity is reached not in average, but in all directions of the upper hemisphere. The statement that average luminous intensity measurements are used by all manufacturers is irrelevant for the purpose of establishing compliance with the said requirements and is furthermore not supported by the results of the tests carried out by the German authorities on four other life jacket lights of other models.

(20) Based on the above considerations and the evidence submitted to the Commission, it is reasonable to conclude that lifejacket lights model Asteria produced by Sic Divisione Elettronica S.r.l. and belonging to batch No 32210805 and No 15202001, do not conform to the applicable requirements for this type of equipment. It must furthermore be concluded that an unknown fraction of the lifejacket lights' production covered by type-approval certificates No MED094008CS/002 and No MED81802CS, regardless of batch or date of production, is not in conformity with the type as a result of the fitting of a bulb which does not meet the relevant specifications. It is not known in which batches, other than the said ones, such bulbs have been fitted.

(21) Life jacket lights are important safety devices, which are used in emergency situations. The luminous intensity of those lights may be of crucial importance. This is especially true in cases where people in distress have to be located in the dusk or dark. A too low luminous intensity may hamper such location. For these reasons minimum requirements have been set and people in distress, rescuers and seafarers should be able to trust that those requirements are met.

(22) The Commission notes that (a) the recall of the product only concerned the German market, (b) it is unknown to what ships under which flags the products have been further disseminated, and (c) the type approval certificates for the product have been withdrawn since 14 April 2011 as reported by RINA.

(23) The duration of a recall in this particular case does not have to be limited until the moment measures have been taken such that the lights do comply with the applicable requirements and may be placed on the market again, since the model Asteria has already been replaced by a another model,

HAS ADOPTED THIS OPINION:

1. The interim measures notified by the German government to the Commission by letter of 25 March 2011 in respect of life jacket lights of model Asteria, manufactured by Sic Divisione Elettronica S.r.l. in the Republic of Italy and belonging to batch No 32210805 or placed on the German market since July 2009, including batch No 15202001, are adequate and proportionate for the protection of maritime safety and are therefore justified. The Commission recommends that the Member States ensure that the life jacket lights of the said model and belonging to the said batches or placed on their markets since July 2009, be removed from their markets.

2. The Commission recommends that the Member States take all appropriate action in order to remove the said life jacket lights from the ships flying their flag and have them replaced by other life jacket lights fulfilling the requirements of Article 5(1) of Directive 96/98/EC.

3. The Commission recommends that the Member States and the notified body RINA take the necessary action to verify that life jacket lights of the model Asteria manufactured by Sic Divisione Elettronica S.r.l., other than those referred to in paragraphs 1 to 3, comply with the requirements of Article 5(1) of Directive 96/98/EC.

4. The Member States should as soon as possible inform the Commission and the other Member States of any measures taken pursuant to this opinion.

Done at Brussels, 6 November 2012.

*For the Commission*

Siim KALLAS

*Vice-President*