

Interinstitutional files: 2017/0353(COD)

Brussels, 27 September 2018

WK 11318/2018 INIT

LIMITE

ENT
MI
CONSOM
COMPET
UD
CHIMIE
COMER
CODEC

WORKING PAPER

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

WORKING DOCUMENT

| From: To: | IT delegation Working Party on Technical Harmonisation (Goods package) |
|--------------|---|
| Subject: | IT comments on the Compliance and Enforcement Regulation Proposal: doc. WK 10325/18 |

IT text proposal on the Austrian Presidency amended text (WK10325 / 2018 INIT of 10th September)

Article 4 (Economic operator responsible for compliance) and 4a (Authorised representative)

IT supports the strengthening of market surveillance, and deems the Presidency proposal a further improvement of the Commission's proposal, more in line with the Decision of the Commission 768/2008, thus ensuring greater regulatory consistency.

The new art. 4 proposal defines more clearly the role of the various actors operating along the value chain of products.

The prerequisite of the whole system is that the extra UE manufacturer has carried out the necessary procedures to correctly drawn up the declaration of conformity, and therefore the economic operator responsible for compliance should be able to verify its correctness.

As a consequence, IT gives full support to the Presidency proposal.

A further improvement could be adding to article 4, paragraph 3, the following (letter (ba) of the proposal AT WK 8193/2018 INIT:

(a) if the Union harmonisation legislation applicable to the product provides for an EU declaration of conformity and technical documentation, verifying that EU declaration of conformity and technical documentation have been **correctly** drawn up and keeping the declaration of conformity and technical documentation at the disposal of market surveillance authorities for the period required by that legislation;

(ba) when considering or having reason to believe that a product in question presents a risk, immediately informing the manufacturer and the market surveillance authority, and where applicable, other economic operators;

Article 5 (Declaration of conformity)

IT would keep article 5, deleted by the Presidency, considering the positive deterrent effect of the Declaration of conformity.

Art. 28 (Release of products)

Italian delegation strongly believe that a piece of law should be clear. Administrative decisions have to be based on facts, data and tests, not adopted on the grounds of opinions or thoughts. The possible cases has to be clearly identified: the Supervisory Authority has not requested to maintain the suspension (a) or the same has expressly approved the release for free circulation (b). As a consequence, we propose the following (very close to the French proposal (WK 9523/2018 INIT):

Where the release of a product for free circulation of a product has been suspended in accordance with Article 27, that product shall be released for free circulation where all the other requirements and formalities relating to such a release have been fulfilled and if any of the following conditions is satisfied:

- (a) within five working days of the suspension, the authorities designated under Article 26(1) have not been requested by the market surveillance authorities to maintain the suspension the absence of answer of market surveillance authorities;
- (b) the authorities designated under Article 26(1) have been informed by the market surveillance authorities that there is cause to believe that the product, when it is placed on the market, will complyies with the Union harmonisation legislation

applicable to it the positive answer of the market surveillance authorities.

A product released for free circulation in accordance with point (a) shall not be deemed to be in compliance with Union harmonisation legislation merely by reason of having been released for free circulation. The release of the product shall not be opposite to the surveillance authority as proof of conformity, especially in the case of release in compliance with the point a).