



EUROPEAN COMMISSION

*Brussels, 30.7.2018
C(2018)5184 final*

Dear President,

The Commission would like to thank the Senat for its Opinion on the proposal for a Regulation of the European Parliament and of the Council on the mutual recognition of legally marketed goods in another Member State {COM(2017) 796 final}.

By proposing this measure as part of the 'Goods Package', the Commission is keeping its promise in the Single Market Strategy to strengthen the Single Market for goods.

The Commission welcomes the broad support for this proposal and has taken due note of the views expressed by the Senat.

On the relationship between this proposal and harmonised Union legislation, the Commission would like to clarify that the proposal would only apply to products, or aspects of products, which are not covered by harmonised rules at Union level.

As regards prior authorisation, the proposal and the procedural guarantees offered therein are not applying to prior authorisations as such, and to the power of Member States to introduce such procedures in their national law. Therefore, administrative decisions denying or restricting market access which are based exclusively on the grounds that the products do not have a valid prior authorisation are excluded from the scope of the proposal. However, when an application for prior authorisation is made, any administrative decision to reject the application based on a national technical rule in that Member State should be taken in accordance with this proposal, so that the applicant can benefit from the procedural protection that the proposal provides.

*Mr Călin POPESCU-TĂRICEANU
President of the Senat
Calea 13 Septembrie nr. 1-3, sector 5
RO – 050711 BUCHAREST*

As regards the need for a two-year transitional period, the Commission considers that the requirements laid down in the proposal would be easy to implement and to conform with, and therefore a long transitional period would be unnecessary and would deprive economic operators from being able to fully rely on the mutual recognition principle and benefit from the potential of the internal market as soon as possible.

In relation to the mutual recognition declaration, the Commission would like to reassure the Senat as regards the risk of confusion between this declaration and the declaration of conformity pursuant to harmonisation legislation. The declaration would always refer to the legal grounds on which it is based, and there is no obligation for the economic operator to present the declarations together. It is only a possibility, to be used by those dealing with partially harmonised products and wishing to simplify the products technical file.

The points made in this reply are based on the initial proposal presented by the Commission, which is currently under discussion between the co-legislators.

The Commission hopes that these clarifications address the issues raised by the Senat and looks forward to continuing the political dialogue in the future.

Yours faithfully,

*Elżbieta Bieńkowska
Member of the Commission*