



Council of the  
European Union

006741/EU XXVI. GP  
Eingelangt am 21/12/17

Brussels, 21 December 2017  
(OR. en)

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**Interinstitutional File:**  
**2017/0354 (COD)**

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15965/17  
ADD 3

COMPET 897  
ECO 82  
MI 991  
ENT 279  
CONSOM 411  
GAF 52  
AGRI 712  
CODEC 2137  
IA 229

## PROPOSAL

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From: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 20 December 2017

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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No. Cion doc.: SWD(2017) 472 final

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Subject: COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY  
OF THE IMPACT ASSESSMENT Accompanying the document Proposal  
for a Regulation of the European Parliament and of the Council on the  
mutual recognition on goods lawfully marketed in another Member State

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Delegations will find attached document SWD(2017) 472 final.

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Encl.: SWD(2017) 472 final



Brussels, 19.12.2017  
SWD(2017) 472 final

**COMMISSION STAFF WORKING DOCUMENT**  
**EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT**

*Accompanying the document*

**Proposal for a Regulation of the European Parliament and of the Council  
on the mutual recognition on goods lawfully marketed in another Member State**

{COM(2017) 796 final} - {SWD(2017) 471 final} - {SWD(2017) 475 final} -  
{SWD(2017) 476 final} - {SWD(2017) 477 final}

<b>Executive Summary Sheet</b>
Impact assessment on Proposal for a Regulation of the European Parliament and of the Council on mutual recognition on goods
<b>A. Need for action</b>
<b>Why? What is the problem being addressed?</b>
The Evaluation has concluded that mutual recognition does not function as it should, due to the lack of awareness, the legal uncertainty and the lack of efficient communication and cooperation among stakeholders. Economic operators don't benefit fully from their existing rights. National authorities lose time and resources. Consumers face higher prices and lower choices. Absent any action at EU level, it is expected for the problem to remain.
<b>What is this initiative expected to achieve?</b>
While the expected benefits cannot be estimated with accuracy, a recent study on "The Costs of Non-Europe in the Single Market" shows that a reduction of trade barriers could lead to an increase of intra-EU trade of more than 100 billion EUR per year. The concept of trade barriers in this study is broader than mutual recognition only, but it provides an estimation of the expected benefits.
<b>What is the value added of action at the EU level?</b>
Having a common set of rules guarantees equal treatment and allows a coherent application of mutual recognition. Action by Member States alone would dismantle the principle in 28 different and potentially contradicting national procedures.
<b>B. Solutions</b>
<b>What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?</b>
The policy options assessed were: <ul style="list-style-type: none"> <li>• Option 2 - Soft law</li> <li>• Option 3 - Minimum legislative changes</li> <li>• Option 4 - Comprehensive legislative</li> <li>• Option 5 - Voluntary prior authorisation to marketing</li> </ul> The preferred option is option 4 complemented by option 2.
<b>Who supports which option?</b>
Option 2 was supported by all, if complemented by other tools. Option 3 was considered potentially effective by all but to a less extent than other options. Option 4 was considered by all as the most effective. There was a consensus against option 5.
<b>C. Impacts of the preferred option</b>
<b>What are the benefits of the preferred option (if any, otherwise main ones)?</b>
Option 4 combined with option 2 will increase awareness and knowledge about mutual recognition, while bringing legal certainty on the application of the principle and improving administrative cooperation among Member States.
<b>What are the costs of the preferred option (if any, otherwise main ones)?</b>
Costs for companies are minimal. Member States and the Commission will bear certain necessary costs, estimated as follows: organisation and coordination of awareness and training events (500 000 Euro), exchange of officials' scheme (170 000 Euro per year), the fast track appeal procedure (3-4 Commission FTEs, 225 000-300 000 Euro per year), increased administrative cooperation (1 200 000 Euro per year).
<b>How will businesses, SMEs and micro-enterprises be affected?</b>
Micro and SMEs will be positively impacted by the initiative without incurring any additional costs.
<b>Will there be significant impacts on national budgets and administrations?</b>
Product Contact Points may be affected as appropriate resources will be needed for the entrusted tasks.
<b>Will there be other significant impacts?</b>
There will be bigger market opportunities for companies, in particular the innovative ones.

#### **D. Follow up**

##### **When will the policy be reviewed?**

The Commission would report to the European Parliament and to the Council five years after the entry into force of the new regulation and every five years thereafter.