

ASSEMBLY OF THE PORTUGUESE REPUBLIC

EUROPEAN AFFAIRS COMMITTEE

PART I - INTRODUCTION

In accordance with Article 7 of Law No 43/2006 of 25 August 2006 on the monitoring, examination and issuing of opinions by the Assembly of the Republic in the context of the process of EU integration, as amended by Law No 21/2012 of 17 May 2012 and in accordance with the Guidelines for the scrutiny of EU initiatives approved on 8 January 2013, the European Affairs Committee has received the Proposal for a Council Regulation amending Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances. [COM (2016) 547].

In view of its subject-matter, the initiative was forwarded to the Health Committee, which examined it and approved the report attached to and forming an integral part of this opinion.

PART II - RECITALS

1. The document in question concerns a proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances.
2. The general objective of this initiative is to regulate at EU level new psychoactive substances that pose health and social risks across the Union.
3. Therefore, it is proposed that this initiative should be combined with the existing legislative framework. In particular, provisions concerning the early warning on new psychoactive substances would be strengthened and the procedures for drawing up an initial report and organising the risk assessment procedure would be made more efficient. Under the proposal the time periods in all phases of the procedure would also be considerably reduced.
4. Lastly, it should be noted that the report drafted by the Health Committee fully reflects the tenor of the initiative. It should therefore be deemed to have been reproduced here in full in order to avoid repetition of analysis and consequent redundancy. The report attached to and forming an integral part of this Opinion is hereby fully endorsed.

a) Legal basis

The legal basis for this initiative is Article 168 of the Treaty on the Functioning of the European Union (TFEU). Paragraph 5 of this Article allows the European Parliament and the Council to 'adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health (...)'.

b) Principle of subsidiarity

As regards the principle of subsidiarity, the conclusion is that the objectives of this proposal for a Regulation, which involve adopting measures concerning monitoring and combating serious cross

border threats to health, cannot be sufficiently achieved by the Member States, and can therefore be better achieved at Union level.

The principle of subsidiarity has accordingly been upheld.

PART III - OPINION

In the light of the information set out above and the report of the Health Committee, the European Affairs Committee is of the opinion that:

1. This initiative upholds the principle of subsidiarity, insofar as the objective will be achieved more effectively by means of action at European Union level.
2. This concludes the scrutiny of this initiative.

Palácio de São Bento, 25 October 2016

Signed:

António Sales - Rapporteur

Regina Bastos - Committee Chair