



Council of the  
European Union

Brussels, 7 December 2016  
(OR. en)

15325/16

COMPET 651  
ENV 779  
CHIMIE 77  
MI 783  
ENT 226  
SAN 426  
CONSOM 309

**'I/A' ITEM NOTE**

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From: General Secretariat of the Council  
To: Permanent Representatives Committee/Council

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No. Cion doc.: 13738/16 COMPET 541 ENV 679 CHIMIE 62 MI 660 ENT 192 SAN 364  
CONSOM 253 + ADD 1

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Subject: COMMISSION REGULATION (EU) .../... of XXX amending Regulation  
(EC) No 1272/2008 of the European Parliament and of the Council on  
classification, labelling and packaging of substances and mixtures by  
adding an Annex on harmonised information relating to emergency health  
response  
– Decision not to oppose adoption

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1. Article 53 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures <sup>1</sup> provides for a procedure to amend the Annexes of this Regulation.

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<sup>1</sup> OJ L 353, 31.12.2008, p. 1.

2. Therefore, in accordance with Article 5a(2) of Council Decision 1999/468/EC<sup>2</sup>, the relevant Committee was consulted on 21 September 2016. It voted with 18 delegations in favour of the above draft Regulation.<sup>3</sup>
3. Consequently, the Commission submitted the above draft Regulation<sup>4</sup> to the Council on 21 October 2016, in accordance with Article 5a(3)(a) of Council Decision 1999/468/EC.
4. Under the regulatory procedure with scrutiny, the Council, acting by qualified majority, may oppose the Commission's adoption of the draft Commission Regulations on the grounds that the draft measures presented by the Commission:
  - exceed the implementing powers provided for in the basic instrument, or
  - are not compatible with the aim or the content of the basic instrument, or
  - do not respect the principles of subsidiarity or proportionality.
5. The delegations were asked on 27 October 2016 to indicate their possible opposition to the draft Regulation before 21 November 2016. One delegation raised a ground for opposition. The issue was therefore inscribed on the agenda of a meeting of the Working Party on Technical Harmonisation on 6 December 2016. At that meeting, an indicative vote showed that there was no qualified majority against the draft measure.<sup>5</sup>
6. The Permanent Representatives Committee is therefore invited to recommend to the Council to confirm, as an "A" item of its agenda, that it is not opposed to the draft Regulation in subject.

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<sup>2</sup> Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23), as amended by Decision 2006/512/EC (JO L 200, 22.7.2006, p. 11).

<sup>3</sup> Six delegations voted against. Four delegations abstained.

<sup>4</sup> doc. 13738/16 + ADD1.

<sup>5</sup> On 6 December 2016, only the EL; UK, PL; LV and BG delegations opposed the draft measure.