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#### NOTE

From:	Presidency
To:	Permanent Representatives Committee
No. prev. doc.:	12917/2/16 REV 2 12918/2/16 REV 2
Subject:	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 and Proposal for a Directive of the European Parliament and of the Council amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug = Preparation of a general approach

1. The market for new psychoactive substances (NPS) has changed dramatically in the past few years and NPS appear in the EU at unprecedented pace posing a risk to public health and safety<sup>1</sup>. Currently, Council Decision 2005/387/JHA<sup>2</sup> establishes the EU-wide system for dealing with NPS entering the European market.

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<sup>1</sup> 24 new substances were reported to the European Early Warning System in 2009, 41 in 2010, 49 in 2011, 73 in 2012, 81 in 2013, 101 in 2014 and 100 in 2015.

<sup>2</sup> Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances (OJ L 127, 20.5.2005, p. 32).

2. On 11 July 2011 the Commission submitted a report on the assessment of the functioning of Council Decision 2005/387/JHA concluding that, while Council Decision 2005/387/JHA was a useful instrument, it was not sufficient, considering the scale and complexity of the problem, and therefore required revision. Subsequently, the Council invited the Commission to table in 2012 a legislative proposal on NPS with a view to revising Council Decision 2005/387/JHA on the basis of findings identified in the Commission's assessment and some additional recommendations outlined in the Council conclusions<sup>3</sup>.

3. On 17 September 2013, the Commission tabled a proposal for a Regulation on New Psychoactive Substances (proposed NPS Regulation)<sup>4</sup> and a proposal for a Directive amending Framework Decision 2004/757/JHA (proposed NPS Directive)<sup>5</sup>. The proposed NPS Regulation has been examined by the Horizontal Working Party on Drugs (HDG) since October 2013.

4. COREPER decided on 27 May 2015 that the discussion on the proposal should no longer be pursued on the legal basis of Article 114 TFEU (related to the improvement of the functioning of the internal market), but on the new legal basis of Article 83(1) TFEU (criminal law) and mandated the HDG to resume its work on that basis including the examination of the possibility to include the temporary bans.

5. On 6 April 2016, there was a second COREPER discussion, during which the change of the legal basis to Article 83 TFEU in the form of a Directive was reiterated and Commission was invited to present a proposal on amending the founding Regulation of the European Monitoring Centre for Drugs and Drug addiction (EMCDDA), by introducing the provisions on the Early Warning System and risk analysis and assessment in this Regulation.

6. On 30 August 2016, the Commission presented such a proposal for a Regulation amending the EMCDDA Regulation (doc. 11520/16), which was further examined by the HDG at its meetings on 7 September 2016, 21-22 September 2016, 11-13 October 2016 and 9 November 2016.

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<sup>3</sup> See doc 17730/11.

<sup>4</sup> See doc. 13857/13.

<sup>5</sup> See doc. 13865/13.

7. On 25 October 2016 DROIPEN examined the draft NPS Directive, where a number of important points were agreed, including that implementing decisions rather than delegated acts should be used for including new psychoactive substances in the definition of drug and that the maximum period for the implementation of national measures should not exceed six months.

8. Following the last discussion on the draft NPS legislation at the HDG meeting on 9 November 2016 and the written procedure organised after the meeting, further comments from delegations were received on the definition of new psychoactive substances, criteria for launching the initial report, criteria for launching the risk assessment report, the content of the risk assessment report, criteria for including the new psychoactive substances in the definition of drug, the terms "health" v. "public health" used in the draft legislation.

9. The Presidency took into account the comments provided to the largest extent possible and launched the last written procedure on the draft NPS legislation with a deadline of 22 November 2016, during which some further comments were still received.

10. Given the extensive debates that have been held on these texts and the progress made, the Presidency aims to obtain a general approach so that the trilogues with the Parliament can finally start<sup>6</sup>.

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<sup>6</sup> In the European Parliament, the ENVI Committee adopted its opinion on 31 January 2014. The LIBE Committee, calling for urgent action, adopted its report on the proposed NPS Regulation and Directive already on 10 March 2014. Those reports were later adopted at the plenary session of the European Parliament on 17 April 2014<sup>6</sup>. On 17 November 2016 the LIBE Committee adopted its report on the proposal on amending the founding Regulation of the European Monitoring Centre for Drugs and Drug addiction (EMCDDA) and received a mandate to start negotiations with the Council on the NPS package.

11. The last point which caused most discussions is the question if and how the criteria of "health and social risks" caused by new psychoactive substances should be incorporated in the legislation. It has been stressed at the HDG meetings and through the written comments that NPS should not fall under the definition of "drug" if only the criterion of social harm they cause was fulfilled. However, social harm caused should be an important complementary element to be taken into consideration when making the above-mentioned decision. The close link between health and social risk/harm caused by new psychoactive substances was also emphasised. At the same time it was pointed out that social risk/harm was often difficult to prove.

12. Taking into account all the above-mentioned considerations the Presidency proposed a compromise, outlined in documents 12917/2/16 REV 2 and 12918/2/16 REV 2 (and included in documents 14809/16 and 14810/16) that:

- A concept of "health OR social risks" is used in the draft NPS legislation when making a reference to the definition of new psychoactive substances in the draft Directive and the criteria for launching the initial report in the draft Regulation. This would allow for the monitoring of a huge number of NPS appearing on the EU market without excluding any relevant substances and would set a low threshold for launching an initial report.
- A concept of "public health risks OR public health AND social risks" is used when making a reference to the criteria for launching the risk assessment report in the draft Regulation and a concept "public health risks AND, where applicable, social risks" is used when making a reference to the criteria for including the new psychoactive substances into the definition of drug in the draft Directive. This would ensure that harm to health caused by the new psychoactive substances is the main criteria, while social harm caused is also taken into consideration. However, social harm cannot be considered as sole criteria for including the new psychoactive substances into the definition of drug.

**13. The Presidency invites COREPER to endorse the following Presidency compromise solution with a view to adopting a following general approach at the (JHA) Council meeting on 8-9 December 2016:**

- **the draft Regulation amending the EMCDDA Regulation as set out in document 14809/16;**
- **the draft NPS Directive as set out in document 14810/16.**