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#### STATEMENT OF THE COUNCIL'S REASONS

Subject: Position of the Council at first reading with a view to the adoption of a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Framework Decision 2004/757/JHA in order to include new pyschoactive substances in the definition of 'drug' and repealing

Council Decision 2005/387/JHA

- Statement of the Council's reasons

- Adopted by the Council on 25 September 2017

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# I. <u>INTRODUCTION</u>

On 17 September 2013, the Commission tabled a proposal for a Directive amending Framework Decision 2004/757/JHA (proposed NPS Directive) and a proposal for a Regulation on New Psychoactive Substances (proposed NPS Regulation).

On 21 January 2014 the European Economic and Social Committee adopted its opinion on the proposed NPS Directive and proposed NPS Regulation.

On 17 April 2014, during its plenary session, the European Parliament adopted its position at first reading on the proposed NPS Directive and proposed NPS Regulation.

COREPER decided on 27 May 2015 that the discussion on the proposed NPS Regulation 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).

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 addition (EMCDDA), by introducing the provisions on the Early Warning System and risk analysis and assessment in this Regulation.

On 30 August 2016, the Commission presented such a proposal for a Regulation amending the EMCDDA Regulation, 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.

On 8 and 9 December 2016, the Council (JHA) adopted the general approach on the proposed NPS Directive and proposed NPS Regulation, set out in doc. 14810/1/16 REV 1 and 14809/1/16 REV 1.

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On the same occasion, the Council gave the mandate to the Presidency to enter into negotiations with the European Parliament with a view to reaching agreement as regards the proposed NPS Directive and proposed NPS Regulation.

Three trilogues were held under the Maltese Presidency. A final compromise was found on 29 May 2017 and the texts of the proposed NPS Directive and proposed NPS Regulation, as issued after the interinstitutional negotiations in doc. 9567/17 and doc. 9566/17, were submitted to COREPER on 31 May 2017.

On 8 June 2017 the LIBE Committee voted and approved the text of the proposed NPS Directive and proposed NPS Regulation as it stood after the interinstitutional negotiations. The Chair of the Committee on Civil Liberties, Justice and Home Affairs (LIBE), Mr Claude MORAES, addressed a letter regarding the proposed NPS Directive to the President of the Permanent Representatives Committee stating that, if this text was to be transmitted formally to the European Parliament as the Council's first reading position for this legislative proposal, he would recommend to the Members of LIBE and subsequently to the Plenary that the Council's first reading position be accepted without amendments in Parliament's second reading, subject to verification by the lawyer-linguists of both institutions.

On 20 June 2017, the Council (General Affairs) reached a political agreement on the proposed NPS Directive . The text of the proposed NPS Directive and proposed NPS Regulation subsequently underwent a lawyer-linguistic revision.

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### II. OBJECTIVE

New psychoactive substances, which imitate the effects of substances scheduled under the UN Conventions, are emerging frequently and are spreading fast in the Union. Certain new psychoactive substances pose severe public health or public health and social risks. The aim of the proposed NPS Directive and proposed NPS Regulation is to tackle such new psychoactive substances on the EU level in a faster and more efficient manner compared to the current system, established by the Council Decision 2005/387/JHA.

## III. ANALYSIS OF THE COUNCIL'S POSITION AT FIRST READING

Several elements in the proposed NPS Directive and proposed NPS Regulation needed indepth discussions in order for an agreement to be reached: the use of delegated/implemented acts for including the most dangerous new psychoactive substances in the definition of drug, the deadline for implementation of national measures and criteria for launching the risk assessment report.

## Delegated acts

The major issue in the interinstitutional negotiations was the issue of including new psychoactive substances in the definition of drug through delegated or implementing acts. The Council was of the opinion that implementing acts were the best instrument for such purpose, while the Parliament indicated that this issue was closely related to citizens' health, and the exclusion of the Parliament from taking such decisions was inappropriate. The Parliament requested to be involved in taking the decisions on including new psychoactive substances in the definition of drug. Following lengthy discussions during the interinstitutional negotiations, the Council agreed to accept that new psychoactive substances are included in the definition of drug through delegated acts in return for securing key changes proposed by the Council to the NPS legislation.

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## Deadline for implementation of national measures

Compared to the original Commission proposal, the Council proposed to shorten the period for the implementation of national measures to ban a specific new psychoactive substance from one year to six months, once the delegated act to include a new psychoactive substance in the definition of drug has been adopted. The Parliament encouraged to further shorten this deadline to three months. As a result of negotiations, the Parliament agreed to accept the deadline of six months for the implementation of national measures so as to ensure that all Member States had enough time to do so, due to different legal systems.

#### Threshold for launching the risk assessment report

The Parliament argued that the threshold foreseen by the Council for launching the risk assessment report, once a joint report on a new psychoactive substance has been issued, was too high ("where the initial report gives indications to believe that this substance may pose <u>severe</u> public health risks or public health and social risks was too high"). Following the discussions on this issue, the Parliament agreed to accept the foreseen threshold, given that it only referred to a possibility/indication of a severe risk rather than an established risk, and that this threshold had to be linked with the criteria foreseen for including the new psychoactive substances in the definition of drug (which envisage that to do so the substances have to cause "<u>severe</u> public health and, where applicable, social risks at the Union level").

#### IV. CONCLUSION

The Council's position at first reading reflects the compromise reached in negotiations between the Council and the European Parliament, facilitated by the Commission. Once adopted, the proposed NPS Directive and proposed NPS Regulation will replace the current system for tackling the most dangerous new psychoactive substances at the EU level established by the Council Decision 2005/387/JHA. The new regime will allow to cut by half the time required to subject to control measures the most dangerous new psychoactive substances at the EU level.

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