Council of the
European Union

Brussels, 20 March 2017
(OR. en)

7077/17
ADD 1

PV/CONS 14

DRAFT MINUTES

Subject:	**3526th** meeting of the Council of the European Union **(General Affairs)**, held in Brussels on 7 March 2017

PUBLIC DELIBERATION ITEMS[1]

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LEGISLATIVE DELIBERATIONS

"A" ITEMS (6785/17 PTS A 19)

"B" ITEMS (6784/1/17 REV 1 OJ CONS 14)

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[1] Deliberations on Union legislative acts (Article 16(8) of the Treaty on European Union), other deliberations open to the public and public debates (Article 8 of the Council's Rules of Procedure).

LEGISLATIVE DELIBERATIONS
(Public deliberation in accordance with Article 16(8) of the Treaty on European Union)

"A" ITEMS

1. Regulation of the European Parliament and of the Council amending Regulation (EU) 2016/399 as regards the reinforcement of checks against relevant databases at external borders [First reading]

= Adoption of the legislative act

PE-CONS 55/16 FRONT 484 VISA 393 SIRIS 169 COMIX 815 CODEC 1854

The Council aproved the European Parliament's position at first reading and the proposed act has been adopted, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. In accordance with the relevant Protocols annexed to the Treaties, the Danish, the Irish and the United Kingdom delegations did not participate in the vote.

(Legal basis: Article 77(2)(b) TFEU).

Statement by Slovenia

"The Republic of Slovenia reaffirms its commitment to implement the provisions of the Schengen Border Code (hereinafter the Code) introducing strengthened checks on persons crossing the external borders of Member States, also on those enjoying the right of free movement under Union law. While the purpose of exercising border checks in this manner is expected to deliver an improvement to control of external borders, to increase Member States' internal security and to prevent terrorism, this will also have other consequences.

By this declaration, Slovenia wishes to draw attention to the potential consequences that will follow from consistent implementation of Article 7(2) of the Code.

The Republic of Slovenia, as a country whose territory is one of the most heavily burdened entry and exit areas enabling access to Member States[2], is fully aware of its responsibility of carrying out border control in the interest of all Member States. In Slovenia's view, checks carried out systematically on all persons crossing the external borders, including those enjoying the right of free movement under Union Law, without targeted checks as a basic principle for efficient border checks and without taking into consideration justified exemptions, is a disproportionate measure in relation to the pursued objective of the change.

Additional doubts to the efficiency of the new provisions of Article 7(2) of the Code are related to the possible transitional period for border checks at air borders that are especially vulnerable part of the external borders.

[2] Relevant statistics: In 2015: 60.906.914 passengers crossed external Schengen border, of those 48.792.665 EU citizens; first half of 2016: 26.842.855 passengers, of those 21.385.972 EU citizens.

The implementation on the scale as specified in Article 7 (2) of the Code will have an adverse effect on passenger flows at external borders as it will also have financial implications for Member States. Slovenia cannot be held ultimately accountable for such outcomes.

Slovenia also welcomes the intention of the European Commission to assess regularly the implementation of the Code, including the consequences of amended provisions, and propose relevant amendments if necessary."

Statement by Croatia

"The Republic of Croatia supports the objective of this Regulation. It is of the opinion that implementing the mechanisms established thereunder will help to strengthen and maintain security throughout the territory of the European Union and the Schengen area, and also contribute to the overall control of our border, that is the external border of the European Union.

At the same time, the Republic of Croatia regrets that these measures are to be implemented not only at the European Union's external borders but also at internal borders between Member States fully applying the Schengen acquis and Member States not yet fully applying the Schengen acquis. The title of the Regulation itself implies its application at the European Union's external borders, not at Schengen borders. For that precise reason, all Member States should have been treated equally. Such a regime will constitute a significant additional burden on the national resources of the Republic of Croatia in terms of the required level of technical and personnel capacities, which could have negative implications for the Croatian economy and the efficient flow of passenger and goods traffic. The Republic of Croatia considers that not even at a symbolic level does such a regime at internal borders contribute to unity in achieving the objectives of this Regulation.

Nevertheless, the Republic of Croatia remains fully committed to consistent compliance with and implementation of the Regulation, and welcomes the European Commission's intention to regularly monitor its implementation and propose relevant amendments whenever it deems this possible.

With a view to ensuring efficient implementation, the Republic of Croatia also recalls the specific situations of certain Member States and invites the European Commission to take steps, in consultation with stakeholders and further to the European Council conclusions of December 2016, to find appropriate solutions to address those specific situations.

The Republic of Croatia therefore has an interest and is actively engaged in finding ways to mitigate the undesired consequences of the measures introduced on the flow of passenger and goods traffic both at its external border and at its internal land border with the Republic of Slovenia and Hungary.

Bearing in mind the Regulation's objective and benefits for the European Union as a whole and the fact that it enjoys the broad support of Member States, the Republic of Croatia, as a constructive Member State, supports its adoption."

2. Directive of the European Parliament and of the Council on combating terrorism and replacing Council Framework Decision 2002/475/JHA and amending Council Decision 2005/671/JHA [First reading]

= Adoption of the legislative act

PE-CONS 53/16 DROIPEN 203 COPEN 367 JAI 1028 CODEC 1790

The Council approved the European Parliament's position at first reading and the proposed act has been adopted, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. In accordance with the relevant Protocols annexed to the Treaties, the Danish, the Irish and the United Kingdom delegations did not participate in the vote.

(Legal basis: Article 83(1) TFEU).

Joint statement by the Council, the European Parliament and the European Commission

"Recent terrorist attacks in Europe have highlighted the need to reinforce efforts to safeguard security while promoting the respect of our common values including the rule of law and respect for human rights. To provide a comprehensive response to the evolving terrorist threat, an enhanced criminalisation framework to combat terrorism need to be complemented by effective measures on prevention of radicalisation leading to terrorism and efficient exchange of information on terrorist offences.

It is in this spirit that the EU institutions and Member States collectively express their commitment - within their respective area of competence - to continue to develop and invest in effective preventive measures, as a part of a comprehensive cross sectoral approach that involves all relevant policies, including in particular in the field of education, social inclusion and integration, and all stakeholders, including civil society organisations, local communities or industry partners.

The Commission will support Member States' efforts in particular by offering financial support to projects aimed at developing tools to tackle radicalisation and through EU wide initiatives and networks, such as the Radicalisation Awareness Network.

The Council of the EU, the European Parliament and the European Commission underline the necessity for an effective and timely exchange of all relevant information for the prevention, detection, investigation or prosecution of terrorist offences between competent authorities in the Union. In this respect, making full use of all the existing Union instruments, channels and agencies to exchange information, as well as a swift implementation of all adopted Union legislation in this field is key.

The three institutions reaffirm the need to assess the functioning of the general EU information exchange framework and to address with tangible actions the possible shortcomings, including in light of the Roadmap to enhance information exchange and information management, including interoperability solutions in the JHA area[3]."

[3] doc. 9368/1/16

3. Draft Regulation of the European Parliament and of the Council on Medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [First reading]

= Adoption of the Council's position at first reading and of the statement of the Council's reasons

6592/1/17 REV 1 CODEC 252 PHARM 5 SAN 70 MI 149 COMPET 137
+ REV 1 ADD 1
10728/3/16 REV 3 PHARM 43 SAN 284 MI 478 COMPET 402 CODEC 977
10728/16 ADD 1 PHARM 43 SAN 284 MI 478 COMPET 402 CODEC 977
approved by Coreper, Part 1, on 01.03.2017

The Council adopted its position at first reading, in accordance with Article 294(5) of the Treaty on the Functioning of the European Union, and the statement of the Council's reasons.

(Legal basis: Article 114 and point (c) of Article 168(4) TFEU).

Statement by France

"The French authorities would like to thank the General Secretariat of the Council and the lawyer-linguists for the translation work done on the draft Regulation on medical devices (MDs).

France supports the adoption of this draft text, which will strengthen the rules applicable to MDs thus improving the protection of the health of patients and users of these products.

Nevertheless, and although improvements were made to the text during the finalisation work, **we would like to draw your attention to the following points**:

- We regret that the amendments made to the transitional provisions of the proposal for a Regulation on medical devices (Article 120) stop short of ruling out the possibility of extending the placing on the market of MDs covered by a certificate of conformity issued under the current Directives when their classification has changed under the Regulation. This had been proposed by some Member States during the discussions and would have meant that as soon as the risk classification of an MD changed, it would be required to undergo a new conformity assessment procedure before it could be placed on the market.

- Likewise, we regret that class IIb active MDs intended to administer and/or remove a medicinal product (Article 52(4)) are not subject to the clinical part of the procedure for assessment of technical documentation (points 4.4 to 4.8 of Annex IX). For reasons of consistency and implementation, it is regrettable that the procedure whereby the notified body draws up the clinical evaluation assessment report (described in points 4.4 to 4.8 of Annex IX) does not apply to such MDs, given that the notified body must draw up this report for each of those MDs under the procedure for consultation of an expert panel (point 5.1(a) of Annex IX). Consequently, we believe that a reference to the application of points 4.4 to 4.8 of Annex IX could have been made in the procedure for consultation of an expert panel in point 5.1(a) of that Annex.

- Finally, the French authorities wish to stress that in the context of vigilance activities, the terms 'seriousness' and 'severity' refer to distinct concepts that cannot be used interchangeably. The concept of 'seriousness' is defined in EU legislation (which results in death, is life-threatening, requires hospitalisation or extension of hospitalisation, etc.). 'Severity', on the other hand, usually refers to the intensity of a reaction or an adverse event (it is also used in Directive 2001/83 to define the unexpected nature of a reaction [an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics]). Moreover, this difference between the terms 'seriousness' and 'severity' is also reflected in the World Health Organisation's definition of a serious adverse reaction. However, these different concepts do not occur in the proposals for regulations, and we would question the relevance of using these terms."

4. Draft Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU [First reading]

= Adoption of the Council's position at first reading and of the statement of the Council's reasons

6593/1/17 REV 1 CODEC 253 PHARM 6 SAN 71 MI 150 COMPET 138
+ REV 1 COR 1
+ REV 1 ADD 1
10729/3/16 REV 3 PHARM 44 SAN 285 MI 479 COMPET 403 CODEC 978
10729/16 ADD 1 PHARM 44 SAN 285 MI 479 COMPET 403 CODEC 978
approved by Coreper, Part 1, on 01.03.2017

The Council adopted its position at first reading, in accordance with Article 294(5) of the Treaty on the Functioning of the European Union, and the statement of the Council's reasons.

(Legal basis: Article 114 and point (c) of Article 168(4) TFEU).

Statement by France

"The French authorities would like to thank the General Secretariat of the Council and the lawyer-linguists for the translation work done on the draft Regulation on *in vitro* diagnostic medical devices (IVD MDs).

France supports the adoption of this draft text, which will strengthen the rules applicable to IVD MDs thus improving the protection of the health of patients and users of these products.

Nevertheless, and although improvements were made to the text during the finalisation work, **we would like to draw your attention to the following point**:

- The French authorities wish to stress that in the context of vigilance activities, the terms 'seriousness' and 'severity' refer to distinct concepts that cannot be used interchangeably. The concept of 'seriousness' is defined in EU legislation (which results in death, is life-threatening, requires hospitalisation or extension of hospitalisation, etc.). 'Severity', on the other hand, usually refers to the intensity of a reaction or an adverse event (it is also used in Directive 2001/83 to define the unexpected nature of a reaction [an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics]). Moreover, this difference between the terms 'seriousness' and 'severity' is also reflected in the World Health Organisation's definition of a serious adverse reaction. However, these different concepts do not occur in the proposals for regulations, and we would question the relevance of using these terms."

"B" ITEMS

8. Multiannual Financial Framework (MFF) 2014 - 2020 Review/Revision: Draft Council Regulation amending Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014-2020

= Agreement in principle
= Request for the consent of the European Parliament
= Draft statements

7030/17 CADREFIN 27 POLGEN 23 FIN 176
+ COR 1
7031/17 CADREFIN 28 POLGEN 24 FIN 177
+ COR 1
+ ADD 1
+ ADD 1 COR 1
+ ADD 2
+ ADD 2 COR 1
14942/16 POLGEN 151 CADREFIN 117
+ COR 1 (hr)
+ COR 2

The Council reached an agreement in principle on the package, and endorsed the statements contained in 7031/17 + ADD1. It took note of the unilateral statements tabled by the Commission and Italy, as well as the intention of the UK and Italy to abstain from the vote when the Council finalizes the adoption of the package. The Council decided to send a request for consent to the European Parliament on that basis.

Statement by the Commission on reinforcing the Youth Employment Initiative and additional measures to help tackling the migration crisis and security issues

"Should the downwards trend in youth unemployment observed since 2013 reverse again, consideration should be given to increase the funding for the Youth Employment Initiative beyond the amount of EUR 1.2 billion agreed in the framework of the mid-term review/revision of the multiannual financial framework (MFF) 2014-2020 by using margins available under the Global Margin for Commitments in accordance with Article 14 of the MFF Regulation. For that purpose, the Commission will report regularly on the observed statistical trends and submit a Draft Amending Budget if appropriate."

Without prejudice to the above, additional margins available should be considered, as a matter of priority, for investing in young people across Europe and for measures helping to address the internal and external dimension of the migration crisis and security issues should new needs arise which are not covered by the existing or agreed funding. The Commission will make proposals to that end if appropriate while keeping in mind the need to maintain sufficient margins for unexpected events and the smooth implementation of already agreed programmes.

Statement by Italy

"Allocating resources where immediate action is needed is a priority for the EU in order to respond efficiently to the needs of its citizens. The midterm review of the current Multiannual Financial Framework (MFF) could have provided with a useful opportunity to do so strengthening the European budget of the Union to tackle the main political challenges of our time.

Italy acknowledges some positive aspects of the Presidency compromise proposal, namely: the refinancing of the Youth Employment Initiative (YEI) and the top-ups for migrations and security. Yet this is not enough if we really want to deliver and meet the expectations of our citizens who expect more economic growth, more jobs, more well-being in Europe. Much more could have been done to deliver on these objectives with a more efficient use of the available funds. However, the proposal on the table contains measures that go in the opposite direction, such as the significant decrease in top-ups for highly significant programs, like Horizon 2020, Connecting European Facility, ERASMUS and COSME, and the downsizing of the extra flexibility proposed by the Commission, which basically disregards the fundamental role the special instruments have played in recent years. This is why we consider the Midterm review a missed opportunity.

The commitment by the Commission, expressed through its declaration of 7 March 2017, to take advantage of future available budget margins for the further funding of YEI, for investing in young people across Europe and for measures helping to address the migration crisis, is a clear sign that our concerns are shared. These concerns have been highlighted also by the European Parliament that we hope will continue to share the priorities indicated by Italy.

With this in mind, considering the importance of completing the midterm review and in a spirit of compromise, Italy lifts its reservation of November 15, 2016. At the same time, we stress once again the need for a deep reshaping of the EU budget, with a view to making it more effective in pursuing the political priorities of the Union. In the framework of the future negotiations for the next MFF, Italy will spare no efforts to this end."