

COUNCIL OF THE EUROPEAN UNION

Brussels, 13 July 2011

10842/11 ADD 1

PV/CONS 34 **TRANS** 169 **TELECOM 84 ENER** 135

ADDENDUM to DRAFT MINUTES

3093rd meeting of the Council of the European Union (TRANSPORT, Subject:

TELECOMMUNICATIONS and ENERGY), held in Brussels on 27 May 2011

DQPG

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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

Directive of the European Parliament and of the Council amending Directive 1. 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products

PE-CONS 3/11 MI 24 SAN 7 ECO 3 ENT 10 CODEC 64

- + COR 1 (de)
- + COR 2 (hu)
- + REV 1 (lt)
- + REV 2 (fi)
- + REV 3 (mt)

The Council approved the amendment set out in the European Parliament's position at first reading and adopted the proposed act amended accordingly, with the Latvian delegation abstaining, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: Article 114 and point (c) of Article 168(4) of the TFEU)

Statement by Belgium, Greece and Italy

"Belgium, Greece and Italy today have systems in place that allow the identification at the point of dispense of all individual packs of medicinal products subject to reimbursement. Belgium, Greece and Italy have requested the introduction of transitional measures for Member States that already have systems with a similar function as the future Union safety feature referred to in the new Point (o) of Article 54 that will be added to Directive 2001/83/EC by the Directive now adopted. Belgium, Greece and Italy note that the second indent of Point (b) of Paragraph 2 of Article 2 of this Directive contains such a provision and conclude that their systems are sufficiently similar in purpose to that of the future Union safety feature to entitle them to an additional transitional period of 6 years for the introduction of the Union safety feature and are therefore in a position to vote in favour of this Directive."

Statement by Latvia

"Latvia supports the objective of the Directive to eliminate, by all practical means, the risk of falsified medicines entering the legal supply chain in the European Union. However, Latvia has concerns regarding the measures chosen to achieve this objective.

Latvia is in favour of application of new safety features to those medicinal products that are in the high risk category of being falsified, namely, prescription medicinal products. Latvia cannot accept the inclusion of non-prescription medicinal products in the scope of application as it would, in our opinion, create disproportionate costs to both operators in the legal supply chain as well as patients.

Taking into account the above mentioned. Latvia abstains from the voting of the adoption of the draft Directive.

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2. Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)

PE-CONS 62/10 ENV 835 MI 525 CODEC 1456

- + COR 1 (de)
- + COR 2 (sv)
- + COR 3 (fi)
- + COR 4
- + COR 5 (es)
- + REV 1 (pt)
- + REV 1 COR 1 (pt)
- + REV 2 (it)
- + REV 2 COR 1 (it)
- + REV 3 (cs)
- + REV 3 COR 1 (cs)
- + REV 4 (et)

<u>The Council</u> approved the amendment set out in the European Parliament's position at first reading and adopted the proposed act amended accordingly, with the <u>Bulgarian delegation</u> abstaining, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: Article 114 of the TFEU)

Commission statement on the scope (article 2(2))

"The Commission interprets Article 2(2) as meaning that electrical and electronic equipment which was outside the scope of Directive 2002/95/EC, but which would be covered by the new Directive, does not need to comply with the requirements of this Directive during a transitional period of eight years.

EEE which was outside the scope of Directive 2002/95/EC, but which would be covered by the new Directive, includes among others EEE covered by:

- the new category 11 in Annex I;
- the new definition of "dependent" in Article 3(2);
- "cables" mentioned in Article 4 and the related definition in Article 3(5);
- two-wheel vehicles which are not type-approved (Article 2(4)(f)).

During the transitional period of eight years, in the Commission's interpretation, it follows from Article 2(2) that Member States are obliged to allow electrical and electronic equipment which was outside the scope of Directive 2002/95/EC, but which would be covered by the new Directive, to continue to be made available on their market."

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Commission statement on the review (article 24)

Pursuant to Article 24, the Commission intends to undertake, no later than three years after the entry into force of this Directive, an impact assessment (review) on Article 2 focussing on the changes in scope of this Directive compared to Directive 2002/95/EC which have not yet been impact-assessed.

This review, followed by a report to the Council and the European Parliament, may be accompanied by a legislative proposal, if the Commission deems appropriate. The extent of the review and of the legislative proposal remains to be determined by the Commission in accordance with its right of legislative initiative, in line with the Treaties.

Commission statement on nano-materials (recital 16 and article 6)

The Commission notes that work towards a common definition of nanomaterials is still on-going and intends to adopt a Commission Recommendation on a common definition for all legislative sectors in the near future. The Commission considers that the RoHS provisions cover different forms (including nanoforms) of the substances which are currently banned and those which will be in the future subject to a priority review under RoHS.

Commission statement on correlation tables

"The Commissions recalls its commitment towards ensuring that Member States establish correlation tables linking the transposition measures they adopt with the EU directive and communicate them to the Commission in the framework of transposing EU legislation, in the interest of citizens, better law-making and increasing legal transparency and to assist the examination of the conformity of national rules with EU provisions.

The Commission regrets the lack of support for the provision included in the 2008 Commission proposal on the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), which aimed at rendering the establishment of correlation tables obligatory.

The Commission, in a spirit of compromise and in order to ensure the immediate adoption of that proposal, can accept the substitution of the obligatory provision on correlation tables included in the text with a relevant recital encouraging Member States to follow this practice.

However, the position followed by the Commission in this file shall not be considered as a precedent. The Commission will continue its efforts with a view to finding, together with the European Parliament and the Council, an appropriate solution to this horizontal institutional issue."

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Statement by Italy

"In Italy's view, the definition of "dependent", in Article 3(2) of the text proposed for adoption, cannot be considered in any way a precedent for other proposals for legislation on this subject, and particularly not for the recasting of the Directive on waste electrical and electronic equipment (WEEE), since the two directives have different legal bases and a different scope as well as differing aims."

Statement by Spain, Estonia, Finland, France, Ireland and Sweden

"The above Member States:

- consider that, as a general rule and in the interests of legal certainty, it is inappropriate
 for the Commission to make interpretative statements on legislative texts, which should be
 comprehensible in themselves;
- note in this regard that the Commission has made a statement on the scope, which is at least in part derived from an interpretation of the phrase "dependent on electric currents or electromagnetic fields in order to work properly" in Article 3(a) of Directive 2002/95, and that the Commission's interpretation is neither universally shared nor supported by the aims or the wording of that Directive;
- regret that the Commission has made this statement and note that it is in any event for the Court of Justice alone to provide authoritative interpretations as to the meaning of Union law."
- 3. Regulation of the European Parliament and of the Council amending Council Regulation (EC) n° 55/2008 introducing autonomous trade preferences for the Republic of Moldova

PE-CONS 13/11 COEST 109 NIS 31 WTO 145 CODEC 549

<u>The Council</u> adopted the above Regulation in accordance with Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: Article 207(2) of the TFEU)

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4. Directive of the European Parliament and of the Council on Alternative Investment Fund Managers and amending Directives 2003/41/EC and 2009/65/EC and Regulations (EC) No 1060/2009 and (EU) No 1095/2010

PE-CONS 60/10 EF 181 ECOFIN 738 CODEC 1293

<u>The Council</u> approved the amendment set out in the European Parliament's position at first reading and adopted the proposed act amended accordingly, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: Article 53(1) of the TFEU)

Statement by the Commission

"In line with the declaration given at the adoption of the supervisory package, as regards the process for the adoption of delegated acts under Articles 67 and 68, the Commission emphasizes the unique character of the financial services sector, following from the Lamfalussy structure and explicitly recognized in Declaration 39 to the TFEU. However, the Commission has serious doubts whether the restrictions on its role when adopting delegated acts are in line with article 290 TFEU."

AGENDA ITEMS

- 3. Proposal for a Decision of the European Parliament and of the Council establishing the first radio spectrum policy programme (RSPP)
 - Progress report 13872/10 TELECOM 91 AUDIO 26 MI 314 CODEC 872 10295/11 TELECOM 69 AUDIO 14 MI 262 CODEC 839

The Council took note of the progress report and the annexed text as set out in doc. 10295/11.

- 4. European Network and Information Security Agency (ENISA)
 - (a) Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 460/2004 establishing the European Network and Information Security Agency as regards its duration
 - Adoption

14322/10 TELECOM 98 MI 344 DATAPROTECT 69 CAB 15 INST 358 CODEC 936

PE-CONS 12/1/11 TELECOM 35 MI 171 DATAPROTECT 24 CAB 26 INST 190 CODEC 506 REV 1

+ COR 1(sl)

10102/11 TELECOM 67 MI 254 DATAPROTECT 51 CAB 32 INST 246 CODEC 804

<u>The Council</u> adopted the proposal for a Regulation extending the duration of the European Network and Information Security Agency (ENISA) as set out in doc. PE-CONS 12/1/11 REV 1. (Legal basis proposed by the Commission: Article 114 of the TFEU)

- (b) Proposal for a Regulation of the European Parliament and of the Council concerning the European Network and Information Security Agency (ENISA)
 - Progress report

14358/10 TELECOM 99 MI 346 DATAPROTECT 70 JAI 794 CAB 16 INST 361 CODEC 943

10296/11 TELECOM 70 MI 263 DATAPROTECT 54 JAI 330 CAB 33 INST 256 CODEC 840

<u>The Council</u> took note of the progress report and the annexed text as set out in doc. 10296/11.

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