

Brussels, 1 June 2022 (OR. en)

> 9187/22 PV CONS 28 RELEX 657

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DRAFT MINUTES

COUNCIL OF THE EUROPEAN UNION
(Foreign Affairs)
16 and 17 May 2022

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MONDAY 16 MAY 2022

Foreign Affairs Council with Foreign Affairs Ministers

1. Adoption of the agenda

The Council adopted the agenda set out in 9021/22.

2. Approval of "A" items

9013/22

a) Non-legislative list

<u>The Council</u> adopted the "A" items listed in 9013/22 including COR and REV documents presented for adoption. Statements to these items are set out in the Addendum.

For the following items the documents should read as follows:

Economic and Financial Affairs

18. Transfer No DEC 11/2022 (Section III – Commission)

Approval
approved by Coreper, Part 2, on 11 May 2022

8445/22 8258/22 + **REV 1 (es)** FIN

b) <u>Legislative list</u> (Public deliberation in accordance with Article 16(8) of the Treaty on European Union)

9014/22

Economic and Financial Affairs

1. Council position on draft amending budget No 3 to the general budget for 2022: Financing of the costs of receiving people fleeing Ukraine

Adoption

approved by Coreper, Part 2, on 11 May 2022*

**B446/22*

8447/22*

8317/22*

FIN

<u>The Council</u> adopted its position on draft amending budget No 3/2022, as set out in documents 8446/22 and 8447/22

Agriculture

2. Regulation laying down transitional rules for the packaging and labelling of veterinary medicinal products *Adoption of the legislative act*approved by Coreper, Part 1, on 11 May 2022



<u>The Council</u> 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. (Legal basis: Articles 114 and 168 TFEU). A statement to this item is set out in the Annex.

3. Decision on the period of application and the equivalence of seed produced in Bolivia

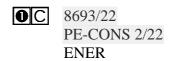
Adoption of the legislative act
approved by Coreper, Part 1, on 11 May 2022

8601/22 PE-CONS 10/22 AGRILEG

<u>The Council</u> 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. (Legal basis: Article 43 TFEU).

Energy

4. Revision of the TEN-E Regulation *Adoption of the legislative act*approved by Coreper, Part 1, on 11 May 2022



<u>The Council</u> approved the European Parliament's position at first reading and the proposed act has been adopted, with <u>Germany</u>, <u>Spain</u>, <u>Luxembourg</u> and <u>Austria</u> abstaining, pursuant to Article 294(4) of the Treaty on the Functioning of the European Union. (Legal basis: Article 172 TFEU).

Telecommunications

5. Regulation on European data governance (Data Governance Act)

Adoption of the legislative act
approved by Coreper, Part 1, on 11 May 2022



<u>The Council</u> 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. (Legal basis: Article 114 TFEU).

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Non-legislative activities

- 3. Current affairs
- 4. Western Balkans *Exchange of views*
- 5. Russian aggression against Ukraine *Exchange of views*
- 6. Any other business

TUESDAY 17 MAY 2022

Foreign Affairs Council with Defence Ministers

Non-legislative activities

- 7. Current affairs
- 8. Implementation of the Strategic Compass with a focus on the future of CSDP missions and operations *Exchange of views*
- 5. Russian aggression against Ukraine *Exchange of views*
- 9. Any other business

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Statements to the legislative "A" items set out in doc. 9014/22

Regulation laying down transitional rules for the packaging and

Ad "A" item 2: labelling of veterinary medicinal products

Adoption of the legislative act

STATEMENT BY DENMARK

"Denmark supports the proposal on amendments to the Commission proposal for a Regulation of the European Parliament and of the Council laying down transitional rules for the packaging and labelling of veterinary medicinal products authorized in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004. Denmark finds it very important that the issues relating to packaging and labelling are resolved swiftly with transitional measures such as the measures proposed. However, Denmark is still concerned that Article 106(1) of Regulation 2019/6 could lead to an unintentional increase in the use of antimicrobials in Denmark and would have preferred if the proposal had also addressed this issue. According to paragraph 1 of Article 106, veterinarians are no longer allowed to deviate from the dosage and the duration of treatment stated in the Summary of Product Characteristics (SPC). Denmark is concerned that veterinarians will be forced to use unnecessarily high amounts of antimicrobials by not being allowed to reduce the duration of treatment stated in the Summaries of Product Characteristic (SPC), even when clinical effect can be achieved by a shorter duration of treatment. An increase in the consumption of antibiotics would be incompatible with the reduction targets in the Farm to Fork-strategy.

The Commission has referred to updating of SPC's as the solution to this issue. However, according to the Danish Medicines Agency it is up to the marketing authorization holder to decide which dosage and duration treatment regime they wish to have covered by the SPC – as long as the safety and efficacy is confirmed by the supporting documentation. Furthermore, if there is evidence to support a need to change the SPC for the above reasons, it is still up to the marketing authorization holder to decide, whether they wish to change the marketing authorization or alternatively deregister the medicinal product, which can lead to supply problems and risk of animal health and welfare. Therefore, until the marketing authorizations have been updated, and for products where the marketing authorizations will not be updated to a sufficient extent, to mitigate these consequences, there is a need for an alternative solution.

Denmark therefore urges the Commission to assist Member States in finding a solution that decreases antibiotic consumption all over the EU."



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