Council of the European Union

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SOC 404
EMPL 218
SAN 490
CONSOM 203
PARLNAT

DRAFT MINUTES

COUNCIL OF THE EUROPEAN UNION
(Employment, Social Policy, Health and Consumer Affairs)

16 June 2026

1. Adoption of the agenda

The Council adopted the agenda set out in document 10342/26.

2. Approval of "A" items

Non-legislative list 10403/26

The Council adopted all "A" items listed in the document above, including all linguistic COR and REV documents presented for adoption.

HEALTH

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

3. European Biotech Act I Directive 1 C 9805/26
General approach + ADD 1-2

The Council reached a general approach on the above Directive as set out in the Annex to document 9805/26.

Austria and Bulgaria presented statements as set out in the Annex to these minutes.

4. European Biotech Act I Regulation 1 C 9454/26
Policy debate

The Council held a policy debate on the above Regulation on the basis of a steering note as set out in the document above.

5. Regulation to simplify rules on medical and in vitro diagnostic devices 1 C 9801/26
Progress report

The Council took note of the progress report on the above Regulation as set out in the document above.

Any other business

6. a) Current legislative proposals (Public deliberation in accordance with Article 16(8) of the Treaty on European Union) ❶C

Critical Medicines Act 6872/25
Information from the Presidency

The Council took note of the information provided by the Presidency.

b) Update on the Recent Ebola Bundibugyo virus (BVD) outbreak in Central Africa 10271/26
Information from the Presidency

The Council took note of the information provided by the Presidency.

c) Impact of the extended producer responsibility under the Urban Waste Water Treatment Directive on the supply of medicinal products 10272/1/26 REV 1
Information from Germany

The Council took note of the information provided by Germany, supported by Austria, Croatia, the Czech Republic, Estonia, Finland, Latvia, Lithuania, Malta, the Netherlands, Portugal, Romania, Slovakia and Slovenia.

d) Presidency conferences 9173/26
Information from the Presidency

The Council took note of the information provided by the Presidency.

e) Negotiations for an international agreement on pandemic prevention, preparedness and response 9406/26
Information from the Presidency and the Commission

f) Work programme of the incoming Presidency
Information from Ireland

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❶ First reading

C Item based on a Commission proposal

Public debate proposed by the Presidency (Article 8(2) of the Council's Rules of Procedure)

Statements to the legislative "B" items set out in doc. 10342/26

Ad "B" item 3): **European Biotech Act I Directive**
General approach

STATEMENT BY BULGARIA

"The Republic of Bulgaria supports the revision of the existing regulatory framework for genetically modified micro-organisms, on the understanding that the precautionary approach is preserved and that a high level of protection of human health, animal health and the environment is ensured, in accordance with the precautionary principle, scientific evidence and proportionality.

Bulgaria welcomes the efforts of the Cypriot Presidency to achieve a more balanced and legally clearer compromise text. In particular, we welcome the clarifications introduced regarding the role of Member States' competent authorities, the monitoring and the limitations placed on the Commission's delegated powers. We consider that these elements contribute to a better balance between fostering innovation and maintaining a high level of protection of health and the environment.

The European Union should remain globally competitive while preserving its high standards of safety and public confidence. In this context, the acceleration or simplification of procedures should not lead to a weakening of risk assessment, of the control powers of competent authorities, or of the risk management system as a whole.

Bulgaria considers it particularly important that the concept of Qualified Presumption of Safety (QPS) does not replace the specific risk assessment of an individual genetically modified micro-organism, including with regard to the characteristics of the genetic modification, the conditions of use and the receiving environment. We also underline the importance of post-market monitoring as an essential element of the regulatory framework, from which exemptions should only be granted on the basis of a duly justified scientific rationale and following an assessment by the competent authority.

Given the dynamic development of science in this field and the existence of elements of scientific uncertainty, Bulgaria considers that any future development of the regulatory framework, including through delegated or implementing acts, should be based on up-to-date scientific evidence, transparent justification and the active involvement of Member States.

Bulgaria acknowledges that, for a number of Member States, issues related to genetically modified micro-organisms remain sensitive from a scientific, regulatory and public policy perspective. We therefore consider it particularly important that the balance achieved within the Council be preserved throughout the forthcoming interinstitutional negotiations.

In this context, and in light of the important improvements introduced into the text by the Cypriot Presidency, Bulgaria is able to support the General Approach. At the same time, we call on the Commission, the incoming Presidency and the European Parliament to preserve the balance achieved and to uphold the key elements of the Council's position relating to scientific evidence, the role of Member States and the maintenance of a high level of protection of health and the environment during the forthcoming trilogue negotiations."

STATEMENT BY AUSTRIA

"Austria would like to thank the Cyprus Presidency for the compromise text on the Biotech Act Directive and for the accommodations made, particularly in the area of organ transplantation. We welcome the consideration given to national frameworks and the efforts made to limit red tape as much as possible. Significant improvements on the original proposal have also been made in relation to the medical applications of genetically modified micro-organisms (GMMs).

However, despite the significant progress made, Austria continues to have serious concerns regarding the placing on the market and release into the environment of GMMs.

Austria welcomes the fact that, instead of the originally envisaged indefinite authorisation following the placing on the market of GMMs, there is now provision for authorisation for an initial period of 10 years.

However, the possibility remains that **monitoring of GMMs eligible for an expedited procedure** would no longer have to be mandatory **once they are first placed on the market**. From Austria's point of view, without mandatory monitoring, there is no substantive basis that can provide scientifically sound justification for an indefinite authorisation. The data required to establish safe use of a GMM following its placing on the market can only be collected through structured monitoring.

As the decision on whether monitoring is mandatory lies with the individual Member State, Austria believes that this could lead to **different practices** in the Member States and thus run **counter to a harmonisation of procedures**.

Austria acknowledges the fact that the proposal contains many improvements. However, in view of the concerns outlined above, we will abstain during the vote on the general approach."