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NOTE

From: General Secretariat of the Council
To: Council

Subject: Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market of genetically modified micro-organisms and the processing of organs
- General approach
= Statement by Austria

Austria has requested that the following statement be entered in the Council minutes.

Statement for the minutes by the Republic of Austria

Coreper I | 3 June 2026

Agenda item 2 European Biotech Act I – Directive

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.