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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 the Republic of Bulgaria

The Republic of Bulgaria has requested that the following statement be entered in the Council minutes.

STATEMENT of the REPUBLIC OF BULGARIA

on

**the 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

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.
