Council of the European Union

Brussels, 9 June 2026
(OR. en)

10004/26
COR 1

LIMITE

SIMPL 128 DENLEG 57
ANTICI 132 MI 570
AGRI 445 FOOD 76
AGRILEG 145 FEED 32
ENV 605 SEMENCES 41
PESTICIDE 43 SAN 380
PHYTOSAN 52 CHIMIE 70
VETER 84 CODEC 1074

Interinstitutional File: 2025/0410 (COD)

PUBLIC

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 852/2004, (EC) No 853/2004, (EC) No 396/2005, (EC) No 1099/2009, (EC) No 1107/2009, (EU) No 528/2012, (EU) 2017/625 as regards the simplification and strengthening of food and feed safety requirements - Mandate for negotiations with the European Parliament

In document 10004/26 INIT,

on page 18, recital 9 should read as follows:

"(9) To accelerate the accessibility and availability to farmers of plant protection products containing new ~~biocontrol~~ **low-risk active** substances, Member States should have the possibility to grant provisional authorisations for such products as soon as the **Authority has launched the public consultation on the** draft assessment report **delivered by the rapporteur Member State** for an application for approval ~~has been delivered~~ concluding that the substance can be approved **meeting the criteria set out in Annex II, point 5, of this Regulation**. When the new ~~biocontrol~~ **low-risk active** substance is approved, and in order to avoid unnecessary administrative procedures, it should be possible to transform such provisional authorisations into regular authorisations without the need of reassessment unless

the conditions set out in the approval require an amendment of the conditions set out in the provisional authorisations. **As regards plant protection products containing as active substances only biocontrol substances, those that can benefit from the provisional authorisation are those which meet the low-risk criteria set out in Annex II, point 5, of this Regulation.**";

on page 23, recital 19 should read as follows:

"(19) The requirement for Member States to consider current scientific and technical knowledge relevant for the active substance in the context of product authorisations has led to some confusion and divergent interpretation among Member State, diverging outcomes of risk assessments, and, as a consequence, unequal access to plant protection products for farmers depending on the Member State of their establishment. It is therefore necessary to clarify that the Member States should normally rely on ~~in~~ the latest active substance assessments at Union level, while also acknowledging that updates may be needed and in such cases the Member States should notify the Commission so that the scientific and technical knowledge is assessed in a harmonised way.";

on page 30, recital 32 should read as follows:

"(32) Article 16 to Regulation (EC) No 396/2005 sets out the procedure for establishing temporary MRLs based on monitoring data, with a mandatory review scheduled within a specified time frame, not exceeding ten years. However, certain MRLs based on monitoring data pertain to active substances that have not been approved in the Union for several decades, and for which residue levels have remained stable over time. Reviewing such temporary MRLs every ten years imposes an unnecessary burden on Member States, food business operators, and the Authority ~~the Authority~~ in terms of data generation and analysis. Given that MRLs can be reviewed at any time under Article 43 of Regulation (EC) No 396/2005, it is appropriate to foresee the establishment of MRLs based on monitoring data on a permanent basis.";

PUBLIC

on page 64, paragraph 2a should read as follows:

"'**2a. For active substances not covered by paragraph 1 which are approved on [OP: please insert the date = 12 months from the date of entry into force of this Regulation], which are not identified as candidates for substitution and for which no renewal procedure is ongoing on that date ~~[OP: please insert the date of entry into force of this Regulation]~~, the Commission shall amend the Regulation referred to in Article 78(3) to extend their approval period**

(a) by 5 years for active substances the approval of which has not been renewed at least once under Article 14;

(b) by 10 years for active substances the approval of which has been renewed at least once under Article 14.'";

on page 83, the first subparagraph of paragraph 2a should read as follows:

"'**2a.** By way of derogation from **paragraph 2,** point (e), where the active substance has one or more of the properties set out in points 3.6.2 to 3.6.5, 3.7.1 to 3.7.3, and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 **or does not meet criteria 3.8.3 or 3.10 of that Annex**, according to the latest available evaluation under Regulation (EC) No 1107/2009 or to a specific evaluation in accordance with Article 43 of **this** Regulation ~~(EC) No 396/2005~~, a MRL ~~that has been set based on a CXL or a GAP implemented in a third country can be revoked and~~ **shall be** set in accordance with Article 18(1)(b) or Article 16 **of this Regulation** ~~if considered appropriate in the light of the outcome of an~~ **based on a prior** impact assessment.'".

PUBLIC