Council of the European Union

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11866/26
COR 1

LIMITE

SIMPL 182 DENLEG 74
ANTICI 191 MI 779
AGRI 589 FOOD 100
AGRILEG 188 FEED 41
ENV 942 SEMENCES 56
PESTICIDE 53 SAN 589
PHYTOSAN 72 CHIMIE 101
VETER 122 CODEC 1445

Interinstitutional File: 2025/0410 (COD)

NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	11412/26
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 - Presidency compromise text

Recital 10 on page 6 of document ST 11866/26 INIT should read as follows:

"(10) To reduce burdens on applicants and Member States and to facilitate the availability of plant protection products containing only ~~biocontrol substances or~~ low-risk active substances **the Union should be considered as one zone for applications for the authorisation of such products. In addition, for products containing only active substances not yet approved in the Union at [OP: please insert the date of entry into force of this Regulation] and which are not candidates for substitution, the applicant should have the possibility to submit the application for the authorisation of a plant protection product containing only such active substances to a single Member State to be evaluated for all zones of the Union. Alternatively, to avoid overly complex assessments in the case of active substances not yet approved in the Union, the applicant may also choose to submit an application to one Member State to evaluate the plant**

protection product for the zone of that Member State ~~the Union should be considered as one zone for applications for the authorisation of such products. Considering also that plant protection products containing only biocontrol substances are not expected to pose different levels of risk in different Member States, mutual recognition of authorisations for such products granted by one Member States should be considered as granted by tacit agreement if decisions on applications for mutual recognition are not adopted within the prescribed deadline~~.”

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