Council of the European Union
General Secretariat

PUBLIC

Brussels, 27 May 2026

WK 7222/2026 INIT

LIMITE

SIMPL	**DENLEG**
ANTICI	**MI**
AGRI	**FOOD**
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ENV	**SEMENCES**
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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus X (Food and feed safety): Explanatory note by the Presidency - AGS meeting on 29 May 2026

In view of the AGS meeting on 29 May 2026, delegations will find enclosed an Presidency explanatory note on the compromise text (9571/26) regarding Regulation (EC) No 1107/2009.

Antici Group on Simplification (AGS)

AGS – 29 May 2026

Omnibus X: Food and Feed Safety, Cluster B, Regulation (EC) No 1107/2009 – Presidency compromise text

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The purpose of this explanatory note is to provide delegations with additional information, clarifications and reasoning for the amendments proposed by the Presidency.
The explanatory note follows the order of the relevant provisions.
This document is for reference only.

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

With a view to the AGS meeting on 29 May 2026, the Presidency is proposing a new compromise text for the recitals and Articles regarding Regulation (EC) No 1107/2009.

Acknowledging the concerns of MS regarding the safety of human and animal health, the Presidency proposes in this **final** compromise text to keep "**unlimited approvals/authorisations" only for low-risk active substances and for products containing them**.
For the rest of active substances (non low-risk), the Presidency proposes to extend their first approval to 15 years (from the current 10) and renewal to 20 years (from the current 15) to deal with the current backlog of ongoing renewal procedures.

Additionally, aligned with the "Vision for Agriculture", PCY supporting the shift towards more sustainable plant protection, proposes to keep, for biocontrol substances, a prioritised approval assessment, as well as the possibility for EFSA to assume the duties of a rapporteur Member State.

In detail, the following changes have been introduced:

Regulation (EC) No 1107/2009	
Recitals	
Recital 5, 9, 10	Changes reflecting the choices proposed by Presidency regarding the **low-risk substances and biocontrol substances.**
Recital 10a and Articles 37(5) and 42	Since the mutual recognition will now be applicable only to low-risk substances, there should be no need for an extended deadline and additional information from the applicant. Moreover, the new wording clarifies that the tacit agreement can be applied only if the MS' national law allows it, but MS need to notify the COM if they cannot apply it.
Recital 14a	The Presidency is now proposing to have **unlimited approvals/authorisations only for low-risk substances**, which means that the deleted text is no longer necessary.
Recital 15	The Presidency is proposing to **delete the amendment to Article 18**, which means that the current Article 18 from R 1107/2009 remains applicable as it is, unchanged. This means that the deleted text about EFSA's advice on planning of a work programme for review/reassessment becomes superfluous.

Recital 22	The Presidency is proposing to **delete the amendments related to treated seeds**, including recital 22.
Articles	
Article 4(7)	New wording clarifying who can request the document evidence necessary to grant the derogation under Article 4(7), by whom and when. The last sentence of the paragraph modifies the phasing out plan by making it optional and without a notification obligation.
Articles 5 and 14	The Presidency is proposing to keep '**unlimited approvals/authorisations' only for low-risk active substances (including biocontrols)**. For the rest of the active substances (non low-risk), the PCY is proposing to extend the 1st approvals to 15 years (from the current 10) and renewals to 20 years (from the current 15 years).
Article 18	Deleted, no longer necessary if there is no unlimited 1st approval for all active substances. This means that the current Article 18 of R 1107/2009 remains applicable as it stands.
Article 18a(1)	Clarification of the criteria to be taken into account when active substances need to be identified for targeted reassessment, as an additional safeguard besides the regular renewal under Article 14 or Article 21.
Article 27a	The new wording adapts this article to the new unlimited approvals for low-risk substances, namely that for the low-risk substances already approved when the amended Regulation enters into force, that approval becomes unlimited, unless the renewal procedure is already ongoing. The new wording in paragraph 3 extends the approval period of active substances by 5 years, to allow extra-time to deal with the current backlog of ongoing renewal procedures.
Article 30	New wording clarifying that provisional authorisations can be applied for low-risk active substances.
Article 32	The article has been adapted to the new unlimited approvals/authorisations for low-risk active substances. For the rest of (non low-risk) active substances, the 2nd subparagraph has been moved first but the meaning is not changed.
Article 36	Replace "*available"* with "*approved*" or "*endorsed*" guidance documents.
Article 49(2a)	New paragraph giving MS the possibility to continue to use plant reproductive material already treated with PPPs whose authorisation has been withdrawn or amended.