Council of the European Union
General Secretariat

PUBLIC

Brussels, 07 May 2026

WK 6491/2026 INIT

LIMITE

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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 13 May 2026

In view of the AGS meeting on 13 May 2026, delegations will find enclosed an Presidency explanatory note on the compromise text regarding Regulation (EC) 1107/2009 (ST 8691/26).

Antici Group on Simplification (AGS)

AGS – 13 May 2026

Omnibus X: Food and Feed Safety, Cluster B, Regulation 1107/2009 – 2nd Presidency compromise text

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

Recitals	
Recital 5	Clarification reflecting the modified definition of biocontrol substances Art 3(35) point d, namely that substances originating from living organisms or derived by biological processes must also meet low-risk criteria.
Recital 6	Further details explaining that the definition of 'biocontrol substances' only includes substances regulating the life processes of plants (with examples) and that 'stimulators' are NOT covered by the scope of R 1107/2009.
Recital 10a	New clarification for the mutual recognition of PPPs containing only biocontrol substances, namely that the MS may ask for additional information and the applicant's deadline for providing it can be maximum 6 months.
Recital 12	Linguistic clarification related to the approval criteria for low-risk substances.
Recital 15	Further clarification related to the implementation of targeted assessments, namely that they should verify both existing and new criteria.
Recital 16	Additional clarification aligning the recital with the modified Article 4(7) related to the possibility of derogations in case of the need to control serious danger to plant health or plant production which cannot be solved by other existing alternatives.
Articles	
Regulation (EC) No 1107/2009	
Article 3 point 27	Modification in the definition for 'greenhouse' clarifying that a greenhouse *effectively restricts* (instead of *severely restricts*) the release of PPPs in the environment. The new additional wording at the end clarifies that open-ended tunnels are not greenhouses, but that closed spaces with opaque outer shell are considered greenhouses.
Article 3 point 34(2)	New wording which further clarifies the definition of *plant biostimulants*.
Article 4(7)	New wording clarifying that MS can ask the applicant for additional information during the approval of a derogation for the approval of an active substance in case of serious danger. Furthermore, the application can only be supported by agricultural official or scientific bodies. The new sentence at the end reinstates this subparagraph already exiting in the current R 1107/2009, for the purpose of fostering research for alternatives.

Article 18	1st para: New wording giving EFSA the mandate to periodically review the scientific literature and the existing monitoring data related to the safety of approved active substances. New obligation for the COM to evaluate at least every 2 years the need to plan a work programme for the renewal procedure of substances with unlimited approvals. 2nd para: clarification that EFSA will the rapporteur for biocontrol substances.
Article 18a(2)(b)	Same as above in Art 18(2), clarification that EFSA may be the rapporteur for biocontrol substances.
Article 23	Para 1(b): Clarification that, for approval as PPPs, basic substances cannot contain co-formulants listed in Annex III. Para 2(b): clarification of the criteria for the approval of basic substances, namely that they should not be '*carcinogenic, mutagenic or toxic for reproduction'*. Para 2(d): clarification in alignment with the approval criteria for active substances set in Article 4, namely that basic substances should not need to have maximum residue limits set for them.
Article 23a	Para 4: Clarification that basic substances and the PPPs containing them can only be used for the uses covered by the approval applications. Para 8: New obligation to label the approved PPP use of a basic substance. The obligation to label does not extend to other uses of the basic substance.
Article 28(2)(g)	Clarifications related to the introduction and use of PPPs sold in another MS in a professional treatment facility only for the purpose of treating seeds.
Article 32(1)	New wording clarifying that MS can still amend or withdraw authorisations.
Article 37 and Article 42	New wording clarifying the steps for the tacit agreement of authorisations of biocontrol and low-risk substances: 1. The MS concerned will have 120 days to grant the authorisation of a PPP containing biocontrol or low-risk substances (already approved by another MS). At the end of 120 days, the MS will publish the authorisation and will send the authorisation number to the applicant. 2. If the MS concerned need more additional information, they can set a new period of 6 months for the applicant to submit it. In this situation, the initial 120 days are suspended and resumed after the submission of the additional information. If the applicant does not provide the additional information before the new 6 month deadline, the authorisation is NOT granted. 3. In the absence of a decision by the MS concerned in the above 120 days (and with the possible max 6 month extension), the authorisation is deemed to have been granted.
Article 49	Para 1: Deleted text removes the sowing of treated seeds from being considered as PPP use. Para 6: editorial changes to align with the wording of R 1272/2008 concerning the labels and documents accompanying treated seeds. Para 7 and 8: due to the deletion in para 1 of the '*sowing of treated seeds'*, the exemptions from certification and machinery used to sow treated seeds are no longer necessary and can be deleted.