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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 1 April 2026

In view of the AGS meeting on 1 April 2026, delegations will find enclosed an explanatory note by the Presidency to the partial Presidency compromise text (ST 7672/26) covering 'cluster B' (with the exception of MRLs and biocides).

Antici Group on Simplification (AGS)

AGS – 1 April 2026

Omnibus X: Food and Feed Safety, Cluster B (without MRLs and biocides) –

1st 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

Recitals	
Recital 8a	New mandate for EFSA to prepare a guidance document to clarify the concept of 'functionally identical and structurally similar' in the definition of biocontrol substances.
Recital 9 and Article 30(1) point aa	Clarification for the moment whence the provisional applications for PPPs containing biocontrol substances can be granted.
Recital 10a	Clarifications for the conditions when mutual recognition for PPPs containing only biocontrol substances can be granted: ➢ similar levels of risks from one MS to another ➢ the assessment has already been made once by another MS ➢ time for assessment period: 120 days + possible extension with max. 120 days
Recital 11	Record keeping for PPPs containing biocontrol substances - Deletion
Recital 14	Linguistic clarification
Recitals 15 and 15a	New text to provide more details on the work programme for the targeted reassessment of active substances and the PPPs containing them. New mandate for EFSA to perform a literature review and advise on the planning of the work programme.
Articles	
Regulation (EC) No 1107/2009	
Article 2(1)(b)	Replace ~~*'disrupting'*~~ with '*regulating*' in the uses of active substances, safeners or synergists: ' (b) '~~disrupting~~ **regulating** life processes of plants, such as substances regulating their growth, other than as a nutrient or a plant biostimulant
Article 3 point 27	Modification in the definition for 'greenhouse' clarifying that a greenhouse *severely restricts* but cannot totally *prevent* the release of PPPs in the environment.
Article 3 point 34	Replace ~~*'disrupting'*~~ with '*regulating*' in the definition of plant biostimulants, similar to PPPs in Article 2(1)(b) above.
Article 3 point 35	New sub-point (c) added to the definition of biocontrol substances, stating that they must fulfil the low-risk criteria set out in Annex II, point 5 of Regulation

	1107/2009. This means that all the priority/fast-track provisions included in the COM proposal will only be applicable to low-risk biocontrol substances.
Article 4(7)	New wording clarifying that the burden of proof is on the applicant, i.e. to produce the evidence necessary for a derogation from the criteria required for the approval of an active substance, in case of serious danger.
Articles 5, 14, 18a	Minor editorial changes
Article 11	Editorial changes
Article 19	Minor editorial change
Article 23(1) point b	Clarification that the approval of basic substances is *not* applicable to *mixtures of basic substances*
Article 28(2) point g	New text for allowing the placing on the market in a MS of PPPs used for seeds treatment if already authorised in another MS.
Article 32	New wording to align the unlimited approval of active substances with the unlimited authorisations of the PPPs containing them.
Article 37 and Article 42(3)	New wording to introduce the possibility for the MS to extend the 120 days proposed for granting mutual recognition of PPPs containing biocontrol or low-risk active substances with an additional maximum of 120 days.
Article 40(1) point c	One-zone approach for biocontrol (*whose definition now clarifies that they must be low-risk*) and low-risk active substances: new wording clarifying that the mutual recognition for PPPs containing only biocontrol or low risk active substances can be granted regardless of the zone of the reference MS.
Article 42(1) point b	New wording introducing the requirement of evidence that a PPP has been sold in the reference MS before applying for mutual recognition in another MS.
Articles 43, 44 and Subsection 4, Article 43a	New text for the targeted reassessment of authorisations of a PPP, after the confirmation of the active substance it contains. Article 43a: ➢ paragraph 2 clarifies the information necessary for the targeted reassessment ➢ para 3 – the MS examining the application needs to check the confirmation of the approval of the active substance and coordinate with the other MS belonging to the same zone which have also received applications for the same PPP ➢ para 4 – MS have max 12 months to authorise a PPP once the active substance it contains has been confirmed ➢ para 5 – the applicant has 3 months (from the moment the active substance is confirmed) to provide to the MS the necessary authorisation dossier
Article 49(6a) and (8)	➢ A new paragraph 6a to introduce implementing acts for Article 49 related to seeds treated with PPPs. ➢ A new paragraph 8 exempting the users of treated seeds and plant reproductive material from the certification requirements foreseen by Directive 2009/128(EC (SUD).
Article 51(2) point c	Editorial change
Article 59	New text introducing an EU database for protected tests and studies.
Article 67(1	➢ Deletion of exemption from record-keeping for biocontrols. ➢ Typo – same sentence twice
Article 81a	Editorial changes

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