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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus X (Food and Feed Safety): Steering and Explanatory Note by the Presidency - AGS meeting on 14 September 2026

In view of the AGS meeting on 14 September 2026, delegations will find enclosed the Presidency Steering and Explanatory Note.



Antici Group on Simplification
14 September 2026
Omnibus X – Steering and Explanatory Note

With a view to the AGS meeting on 14 September 2026, the Presidency is proposing a further revised compromise text for Omnibus X (Food and Feed Safety) in ST 12792/26. Changes are marked in comparison to the previous version (ST 11866/26+COR 1) and highlighted in yellow. The changes are based on interventions made by delegations during the previous AGS meetings on 9 and 20 July. The Presidency has made some new amendments and reinstated some provisions which had been proposed for deletion in the previous version.

The Presidency notes that there are still points of divergence among the Member States and asks delegations to approach the text in a spirit of compromise. The Presidency invites delegations to indicate any remaining red lines.

Explanation of Changes

Regulation No 1107/2009 (PPPs)	
Recital 10	Related to the ' <i>one-zone</i> ' application for authorisation of PPPs containing active substances approved in the Union for the first time, the new wording explains that a Member State has the possibility to decline the application if the application is overly complex and risks to create excessive delays. (linked to Article 33(2)(b))
Recitals 15 and 15b	Additional safeguard meant to further balance the longer approval periods of active substances and to support their targeted reassessment, when necessary: the Commission must give EFSA a mandate to periodically review scientific literature and monitoring data on already approved active substances. The similar wording in recital 15b (where the mandate was a possibility, not an obligation) has been deleted and moved to recital 15 as an obligation, in order to link the review of scientific literature to the targeted review of active substances which are already approved. This should complement the existing provisions of Article 21 related to the possibility of a review of approved active substances.
Recital 26 and Article 27a(2b)(e)	Reinstated inclusion of active substances which are classified as ' <i>carcinogen category 2, mutagen category 2 or reprotoxic category 2</i> ' (CMR cat. 2), in the list of already approved active substances whose approval will NOT be extended once this proposal enters into force.
Article 14(2)	Reinstated possibility to set shorter approval periods for certain active substances where there are scientific uncertainties and/or data gaps.
Article 18a(1) and (2)	EFSA will be given a mandate by the Commission to periodically review scientific literature and monitoring data on already approved active substances (see also recital 15). This is no longer facultative but an obligation. Additionally, the optional provision in paragraph 2 for EFSA to act as Rapporteur for the targeted reassessment of approved active substances is deleted and transformed into an obligation, and moved at the end of the previous paragraph.



Article 33(2)(b)	Editing changes, plus the introduction of the possibility for Member States to decline 'one-zone' applications. The applicant will submit a complete dossier for a whole EU application only if the Member State is prepared to deal with it (see also recital 10).
Article 40.1(c)	Editing changes for better clarity.
Article 53(1)	Editing to better clarify the possibility for a MS to use the detailed information from another MS from the same zone in its decision to grant a similar emergency authorisation.
Article 59	Paragraphs: (6) Proposal to extend the data protection for test and study reports from 10 to 13 years for the 1 st authorisation of regular PPPs and to 15 years for low-risk PPPs. (6a) and (6b) – clarification of the wording to better clarify the uploading of protected test and study reports on an EU platform to be set up by the Commission. (7) wording (moved from paragraph 10) proposing that the successive extensions of PPPs authorisations for minor uses cannot exceed 17 years for low-risk PPPs and 16 years for the other regular PPPs. (11) New implementing rule for the Commission to propose the rules for the functioning of the EU platform for data protection.
Article 81a(6)	Editing changes, plus the reinstatement of the active substances which are 'carcinogen category 2, mutagen category 2 or reprotoxic category 2' (CMR cat. 2) substances in the list of already approved active substances whose approval will NOT be extended once this proposal enters into force (see also recital 26).

Regulation No 396/2005 (MRLs)	
Recitals 27 and 29	Reinstated wording, as in the Coreper text from 12 June 2026 (10004/26 +COR1).
Article 14(2a)	Reinstated wording, as in the Coreper text from 12 June 2026 (10004/26 +COR1).