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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 9 July 2026

In view of the AGS meeting on 9 July 2026, delegations will find enclosed the Presidency Steering and Explanatory Note on the new Presidency compromise text (ST 11412/26).

Steering and Explanatory Note

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Antici Group on Simplification

Omnibus X (Food and Feed Safety)

9 July 2026

Steering Note

With a view to the AGS meeting on 9 July 2026, the Presidency is proposing a new compromise text for Omnibus X (Food and Feed Safety). Acknowledging the significant progress made by the Cyprus Presidency on this file, the Presidency has made changes primarily to the recitals and Articles relating to Regulation (EC) No 1107/2009, with minor changes also made to those relating to Regulation (EC) No 1831/2003 and Regulation (EU) No 528/2012.

These changes have been made in response to calls from Member States to further accelerate access for innovative substances and reduce administrative burdens, while ensuring appropriate safeguards in terms of human and animal health, and environmental protection. These changes will help facilitate market access for new substances and products including, but not limited to, biocontrol substances. Certain provisions have been removed due to concerns from Member States, including some provisions on tacit agreement.

An overview of the changes can be found below. The Presidency invites delegations to indicate, in the spirit of compromise, if they can support this revised text, with a view to the swift agreement of a COREPER mandate for negotiations with the European Parliament. If they cannot, delegations are invited to share concrete suggestions for improvements.

The discussion will proceed in two rounds:

<u>First Round</u>

- Risk management measures (Article 4.1 and 4.3)
- Renewal period, where there are uncertainties, can be of shorter duration (Article 14(2)
- Clarification of criteria for targeted reassessment (Article 18a(1))
- Mandating of EFSA to review where necessary (Article 21(1), Recital 15b)
- Removal of delayed application (Articles 27a, 9(8a), 9a, 14a, 81a; Recital 14, 26, 42, 43, 44)
- Alignment of approval periods for the already approved biocidal active substances to the new approval durations (Recital 34)

Guiding question: Do delegations consider that these changes bring a satisfactory balance of simplification with adequate safeguards?

<u>Second Round</u>

- One-zone approach for low-risk substances (Article 33(2)(b))
- Mutual recognition based on one zone approach for newly approved substances (Article 40(1)(c))
- Removal of tacit agreement (Articles 37(5) and 42(3); Recital 10 and 10a)
- Emergency derogations (Article 53(1))

Guiding question: Do delegations consider that these changes bring sufficient simplification?

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Explanation of Changes

Recitals	
Recital 4	The Presidency is proposing to extend the scope of simplification and to incentivise innovation by facilitating market access for **all new active substances** (including but not limited to biocontrol active substances).
Recital 7	Editing clarifications.
Recital 10	A new measure intended to further reduce the administrative burden and facilitate market access for PPPs: **possibility** to apply for the authorisation of a PPP to **one single MS for the entire EU**, or **for only the zone of that MS** (see Article 33(2)(b))
Recital 10a	The Presidency is proposing to **delete** mutual recognition by **tacit agreement**. (see Articles 37(5) and 42(3))
Recitals 14, 26, 42, 43 and 44	Editing clarifications related to the Presidency's proposal to **delete** the previously introduced **delayed application** of the amendments to Regulation (EC) No 1107/2009 by 12 months (see Articles 27a and Article 81a)
Recital 15b	The Presidency is proposing to allow the **Commission to mandate EFSA to review the scientific literature and monitoring data** for approved active substances, when deemed necessary.
Recital 34	**Alignment of approval periods** for the already approved **biocidal active substances** to the new approval durations proposed for 1st approvals.
Articles	
Regulation (EC) No 1107/2009	
Article 4(1) and 4(3)	Clarification that new technical knowledge can include new innovative PPP application techniques.
Article 14(2)	New wording clarifying that the **renewal of approval of active substances** for which there are uncertainties emerging from their risk evaluation **could be shorter** than the maximum 25 years.
Article 18a(1)	Clarification that the **criteria** to be taken into account to **identify active substances for targeted reassessment do not have to be met all at the same time**. There may be only one, OR several criteria applicable to trigger the targeted reassessment of an active substance.
Article 21(1)	The Presidency is proposing to allow the **Commission mandate EFSA to review the scientific literature and monitoring data** for approved active substances, when deemed necessary (see Recital 15b)

Article 27a	Paragraph 2a: Editing clarifications. Paragraph 2b: list of already approved active substances whose approval will NOT be extended once this proposal enters into force.
Article 27a and Article 81a	Editing clarifications related to the Presidency's proposal to **delete** the previously introduced **delayed application** of the amendments to Regulation (EC) No 1107/2009 by 12 months (see Recitals 14, 26, 42, 43, 44)
Article 33(2)(b)	The Presidency is proposing a **one-zone approach for low-risk active substances**, with a single MS evaluating (see Recital 10).
Articles 37(5) and 42(3)	The Presidency is proposing to **delete** mutual recognition by **tacit agreement** (see Recital 10a).
Article 40(1)(c)	The Presidency is proposing the option for **mutual recognition for PPPs containing only new active substances which are approved for the first time in the EU regardless of zone.**
Article 53(1)	The Presidency is proposing the **possibility for MS to grant the same emergency authorisation as another MS from the same zone.**
Regulation (EC) No 1831/2003	
Articles 9(8a), 9a, 14a	Editing clarifications related to the Presidency's proposal to **delete** the previously introduced **delayed application** of the amendments to Regulation (EC) No 1831/2003 by 12 months.

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