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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus X (Food and feed safety): discussion note by the Presidency (AGS on 6 March 2026)

Delegations will find enclosed a discussion note by the Presidency for the AGS meeting on 6 March 2026 regarding the proposals for Omnibus X (Food and feed safety) related to cluster B.

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Presidency Steering Note

AGS on 6 March 2026

Omnibus X (Food & feed safety) cluster B

This Steering Note was prepared by the Presidency in view of the continued discussions in the Antici Group on Simplification (AGS) on the Omnibus package X, cluster B (pesticides related issues). It builds on the written comments submitted by Member States. The objective is to take stock of emerging views and seek guidance from delegations to allow the Presidency to move towards the drafting phase.

The questions presented below for each issue are intended to steer the discussion and to make progress on the file.

1. SUSTAINABLE USE DIRECTIVE, Delegated Act for drones – 4-year timeline

A. Background

Document WK 2949/2026 sets out the background for the 4-year timeline proposed for the adoption of the delegated act foreseen in Article 9a(2).

B. OPTIONS

Member States will be invited to express their preference for one of the following 3 options:

Option 1: Commission proposal: 4 years under Article 9a(2) for the DA

Option 2: Presidency compromise text (ST 6877/26) - 3 years under Article 9a(2)

Option 3: other time period, please specify.

2. BIOCONTROL SUBSTANCE DEFINITION

A. Background

The current definition:

'35. 'biocontrol substance' means:

(a) micro-organisms,

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(b) inorganic substances as occurring in nature, with the exception of heavy metals and their salts or

(c) substances of biological origin or produced synthetically that are functionally identical and structurally similar to them.

Issues:

1. Many MS consider the current definition too wide and potentially including substances with a toxic mode of action or with hazardous properties which they don't want to see benefiting from the fast-track approval.
2. Several MS have asked to clarify the meaning of "functionally identical and structurally similar".

Some examples are provided below:

Substance	Functionally identical	Structurally similar	Notes
Pyrethroids	Y	N	They have undergone significant structural modifications, particularly at their active sites, compared to their naturally occurring counterparts: pyrethrin and nicotine
Neonicotinoids	Y	N	
Glyphosate	N	N	Apart from having undergone significant structural modifications compared to glycin, Glyphosate exerts a different biological function than its natural counterpart, therefore it is not functionally identical either.
Azoxystrobin	Y	N	Compared to naturally occurring strobilurins, azoxystrobin is a much more complex molecule with significantly increased molecular weight.

B. OPTIONS

Member States are invited to express their preference for one of the following 3 options:

Option 1 – Guidance document developed by EFSA to explain structural similarity

This option addresses the concerns regarding structural similarity.

- Definition remains unchanged, as in the Commission proposal
- The guidance document would clarify that a chemical modification should not trigger additional structure change making the substance potentially of concern.

- The applicant will demonstrate structural similarity with, for instance, *in silico* data which are commonly used to spot the toxicity of metabolites for instance (QSAR).
- RMS should assess it and confirm that the requirement for structural similarity is fulfilled.
- The Commission should confirm it via the list of biocontrol substance foreseen in Article 13(4).

Option 2 – Biocontrol substances must fulfil low-risk criteria to benefit from regulatory simplification *This option addresses the concerns regarding to the possibility that the biocontrol definition (as it stands) could potentially include hazardous substances and that they would end up benefitting from priority assessment.*

- The definition of biocontrol substances will be complemented by an additional sub-point (c) stating that an active substance must fulfil the low-risk criteria set out in Annex II, point 5 of Regulation1107/2009:

> *(c) "substances of biological origin or produced synthetically that are functionally identical and structurally similar to them* ***and meet the criteria set out in Annex II, point 5, to this Regulation****."*

- This means that biocontrol substances will have to meet low-risk criteria to benefit from the proposed simplification measures (fast-track approval or provisional authorisation)

Option 3 – Guidance document + Biocontrol substances fulfilling low-risk criteria
This is a combination of Options 1 and 2. It addresses both the concerns regarding structural similarity and regarding the possibility that the biocontrol definition (as it stands) could include potentially hazardous substances.

3. TACIT AGREEMENT when a decision by a MS on a PPP containing only biocontrol or low-risk substances is not adopted within 120 days

A. Background

The Commission proposal foresees tacit agreement for zonal/mutual recognition for authorisations, where the Member State has not adopted a decision within the deadline of 120 days provided in the new Articles 37(5) and in the amended Article 42(3).

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B. OPTIONS

Member States are invited to express their preference for one of the following 3 options:

Option 1 – Commission proposal

The proposal aims to facilitate the placing on the market of biocontrol substances as alternatives to chemical active substances, since PPPs containing only biocontrol or low-risk substances are not expected to pose different levels of risk in different Member States.

Option 2 - decision does not necessarily mean authorisation

Provide in the recitals a clarification that "decision" may mean a reaction related to the procedure (such as further extension, request for more documents, etc.), the final authorisation or non-authorisation.

Rationale:

- This would give the Member States the flexibility to extend the 120 days by informing the applicant that more time for the assessment is necessary. Only in case the Member State does not react in any way, the tacit agreement would be presumed.
- However, it can be expected that in most cases the 120 days would be extended, even multiple times. Therefore, in order to maintain the effectiveness of the tacit agreement, the Presidency is proposing to limit the possibility of extensions to another 120 days.

Option 3 – 180 days

Instead of the 120 days period foreseen by the Commission proposal, the Member States would have 180 days before the tacit agreement becomes applicable.

4. APPROVALS AND AUTHORISATIONS

A. Background

Omnibus X package is proposing unlimited approval of active substances (with clear exceptions) combined with limited (max 15 years) PPP authorisations. The Commission and MS will periodically select substances with unlimited approval periods for full renewal or targeted reassessment. The possibility for review at any time (Art. 21) and emergency measures (Art. 69) is maintained.

B. OPTIONS

Member States are invited to express their preference for one of the following 3 options:

Option 1 – Commission proposal

Unlimited approvals (except substances that are candidates for substitution and those approved under Article 4(7)) + **limited authorisations (maximum 15 years)**

Rationale:

- Most approved active substances have gone through at least one renewal process and new active substances are expected to have better toxicological and ecotoxicological properties
- the possibility for ad-hoc reviews already foreseen in Art. 21 is maintained
- it is still possible to set time limits for approvals if found appropriate following a risk assessment
- Under Article 27a, all ongoing procedures for approval/renewal of approval will continue and be completed (~ 200 substances). The end of each of these procedures will decide whether the active substance concerned will (or will NOT) be granted unlimited approval/renewal.
- The Commission, taking into account requests from Member States, may identify active substances with unlimited approval for which a full renewal procedure will be carried out, or identify active substances with unlimited or limited approval periods for targeted reassessment
- **The advantage**: more efficient use of resources for the MS and EFSA, as they would be able to dedicate their resources to:
    1) those active substances for which there is a justification for re-evaluation
    2) the assessment of applications for the approval of new active substances and for the authorisation of PPPs containing them.

Option 2 – both unlimited

Unlimited approvals (with the same exceptions as in Option 1) + **unlimited authorisations**

Rationale:

- Option 1 rationale still applies
- **In addition to option 1**:
    1) more flexibility for the MS and EFSA to dedicate their resources to the approval of new substances and the authorisation of the PPPs containing them.
    2) compared to Option 1 (where, after max 15 years, all PPPs would have to be re-assessed and re-authorised), the full renewal or targeted reassessment will only be done on the basis of the work programme established by the Commission and MS. The full renewal or targeted reassessment of PPPs will be decided following the renewal of the active substances they contain,

when justified by new data, new scientific knowledge or technological progress.

3) The potential backlog created by the automatic re-authorisation process after 15 years would be diminished.

Option 3 – both unlimited ONLY for low-risk substances and PPPs containing them
Unlimited approvals (with the same exceptions as in Option 1) + **unlimited authorisations only for low-risk substances** (including low-risk biocontrols) and PPPs. For the rest of active substances and PPPs, the current system foreseen by Regulation 1107/2009 would continue to apply (i.e. all active substances would be limited in time except low-risk ones).

Rationale:

- Option 3 would be more cautious and more limited than Option 2, as the unlimited authorisation of PPPs would only be possible for low-risk active substances (and the PPPs containing them).

5. DELINEATION OF PLANT PROTECTION PRODUCT ACTIVE SUBSTANCE FROM PLANT BIOSTIMULANT

A. Background

The Commission proposal changes the definition of active substance for plant protection from the wording *"influencing life processes"* (foreseen in the current Regulation 1107/2009) to "*disrupting life processes"*. Several MS have pointed out that this change might move some active substances (e.g. plant growth regulators) to the plant biostimulants regulatory framework (Fertilising Products Regulation), as they are not disrupting but rather regulating life processes by positively stimulating plant growth via hormone-driven pathways.

B. OPTIONS

Member States are invited to express their preference for one of the following 2 options:

Option 1 – Commission proposal
Article 2 is amended as follows: (a) paragraph 1, point (b) is replaced by the following: '(b) 'disrupting life processes of plants, such as substances regulating their growth, other than as a nutrient or a plant biostimulant'

Option 2 – replace 'disrupting' by 'regulating'
Article 2 is amended as follows: (a) paragraph 1, point (b) is replaced by the following: '(b) '~~disrupting~~ **regulating** life processes of plants, such as substances regulating their growth, other than as a nutrient or a plant biostimulant'

6. PROVISIONAL AUTHORISATIONS

A. Background

The Commission proposal provides in Article 30 the possibility for Member States, by means of a derogation, to authorise the placing on the market of plant protection products containing one or more biocontrol active substances not yet approved, provided that specific conditions are fulfilled, and extending the provisional period from 3 to 5 years. The rationale lays in accelerating the access of biocontrols on the market, which remains in any case optional for MS.

Nevertheless, some MS expressed concerns on the stage of assessment triggering the possible provisional authorisation, the moment from which onwards a provisional authorisation can be granted, while others raised the concern of workload for MS due to the provisional authorisations.

B. OPTIONS

Based on the above background, Member States are invited to express whether they:

Option 1: support Commission's proposal;

Option 2: support provisional authorisations for a time period not exceeding 5 years for plant protection products containing biocontrol active substances

7. DATA PROTECTION

A. Background

The Commission proposal amending Article 59 provides for an **EU-wide data protection period**, The aim is to address the lack of transparency in terms of when data protection for a given test or study report expires in the different Member States and to set the same data protection period across the Union. This would result at an equal distribution of PPP regardless the size of the Member States

Some MS expressed doubts whether that the new provision covers data submitted for the amendment of the authorization and that it would be difficult to manage at national level. Furthermore, it should be clarified how MS will verify the data protection status and whether such has been granted anywhere in the EU

The Commission has provided the following clarifications regarding the new data protection regime:

- The assessment in the EU is zonal and not per Member State. Therefore, there should be no major differences in the authorisation timeliness between the Member States from the same zone

- The data protection is granted study per study and not per dossier. As long as a study is submitted in one Member State and data protection is granted, this is also granted in the whole EU.
- The burden of proof that the data is protected and that the letter of access is granted by the data owner is for the applicant
- A procedural framework could be defined in an implementing act or an updated technical notice on data protection which may include elements such as: the tracking of data protection via a platform, a mechanism for tracking and access to which MS and for which time period the data protection exist.

B. OPTIONS

Based on the above background, Member States are invited to express whether they:

Option 1: support Commission's proposal;

Option 2: Propose a new alternative, other than the Implementing Act above (please specify)

8. INCLUSION OF SOWING OF TREATED SEEDS AS A USE OF PPPs – Art. 49

A. Background

The Commission proposes that the treatment of seeds and plant reproductive material with plant protection products as well as the sowing of the treated seeds and plant reproductive material constitute a use of a plant protection product.
The reason is the current lack of clarity in the classification of sowing of treated seeds which has created disparity among Member States and barriers to the circulation of treated seeds.

B. OPTIONS

Member States are invited to express their preference for one of the following 2 options:

Option 1 – Commission proposal

The classification of sowing of treated seeds remains unchanged.

Rationale:

- The sowing has always been subject to risk assessment both at Member State level and at EFSA level.
- Nothing changes in the free movement of seeds in the EU as the derogation in Article 49 is kept and even further clarified in the new point f of Article 28 (2).
- The proposed amendment does not suggest that the treated seeds themselves are a PPP. This means that the rules applicable to storage, transport, insurance of PPPs are not and will not be applicable to treated seeds.

- The sowing of treated seeds constitutes a use of PPP for which exposure of operators and the environment occur e.g. via dust or direct contact with soil or water or because of delayed effects of the PPP manifesting only after germination.
- The measures would not create additional burden for the seed treatment industry. The administrative burden for the farmers should be limited as the specific derogation for the machinery used for sowing (as proposed in paragraph 7) will not be regarded as pesticides application equipment within the meaning of Directive 2009/128/EC56 on the sustainable use of pesticides.

Option 2 – exemption from certification for treated seeds

Insert a provision exempting the use of sowing treated seeds and plant reproductive material from the certification requirements for professional users under Directive 2009/128/E

- This would alleviate the users' obligations. However, it should be noted that the sowing of treated seeds/planting of other plant reproductive materials treated with pesticides poses a certain risks for operators, bystanders and the environment.
- Users should be informed and trained about the above risks. Labelling (paragraph 6) should help in this respect

Option 3 – delete the provision

Remove the provision clarifying the sowing of treated seeds and plant reproductive material (PRM) is use of a PPP, due to concerns related to the increased administrative burden.

9. EXTENSION OF AUTHORISATIONS FOR MINOR USES – Art. 51

A. Background

The Omnibus X package proposes to remove some of the conditions for obtaining authorisations for plant protection products for minor uses set out in Article 51 (such as the specific condition of "public interest").

The proposal also reinforces mutual recognition: whereas in the current regulation MS were invited to take measures to facilitate or encourage the submission of applications *(Member States may take measures)*, the amendment of article 51(3) creates a new obligation *(Member States shall take measures)*

Furthermore, it proposes that the Commission be empowered to adopt implementing acts harmonising the procedures for granting extensions of authorisations for minor uses and for authorisations by mutual recognition in order to achieve more harmonised availability of PPPs for minor uses (new paragraph 9).

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B. OPTIONS

Member States are invited to express their preference for one of the following 3 options:

Option 1 – Commission proposal

Rationale:

- The conditions for obtaining authorisations for PPP for minor uses have proven to be too restrictive
- The implementation of the article varies significantly across Member States
- It is in particular necessary to waive the specific condition of "public interest", as in some Member States there is a steady interpretation what is "public interest" stemming from national case law which is very restrictive and makes the use of this article difficult.

Option 2 – Remove the amendments of Article 51

Rationale:

- The restrictions to the extension of authorisation have not been sufficiently proven and detailed
- The "public interest" condition has to be seen as a necessary safeguard

Option 3 – Going beyond the reinforcement of the effectiveness of mutual recognition

Minor uses are defined per Member State (crop/pest combination). One and the same crop could be minor use in one MS and major in a neighbouring MS (oranges are major in Spain and minor in France, even though both belong to the Southern zone).
Replace the proposed amendment of Article 51(3) by a **new provision** considering that an extension of authorisation granted by a MS for a specific Crop / Pesticide / Disease combination and subject to the provision of appropriate risk management measures and distribution techniques by the MS, may be immediately applicable in another Member States of the same zone with the same crop/pesticide/disease combination.

Rationale:

- Immediate effectiveness in mutual recognition is necessary in order to achieve more harmonised availability of plant protection
- Restrictive conditions would act as safeguard: the immediate effectiveness would be applicable only for be applied for a specific Crop / Pesticide / Disease combination and subject to the provision of appropriate risk management measures and distribution techniques by the MS

10. RECORD KEEPING FOR PPPs CONTAINING BIOCONTROL SUBSTANCES – Article 67(1)

A. Background

In order to reduce the administrative burden for farmers, the Omnibus X package is proposing that the general obligation professional users of plant protection products have to keep records of their use during at least three years shall not apply to PPPs containing biocontrol substances. This exception does not apply to producers and distributors of PPPs containing biocontrol substances, which will continue to comply with the obligation of keeping records for 5 years of the PPPs they produce and place on the market.

B. OPTIONS

Member States are invited to express their preference for one of the following 2 options:

Option 1 – Commission proposal

No record keeping of PPPs containing biocontrol substances

Rationale:

- Such information is less relevant as records of the use of PPPs are kept in order to raise the protection of human and animal health and the environment by ensuring the traceability and potential exposure to increase the efficiency of monitoring and control to reduce the costs of monitoring water quality
- Administrative burden is reduced for farmers
- Facilitates the use of products containing biocontrol substances
- Sales data for biopesticides will continue to be collected, trends in their use can still be estimated, even without record keeping by individual users

Option 2 – remove the exception for biocontrol substances

Maintain the record keeping obligations for the use of all PPPs, including those containing biocontrol substances

Rationale:

- Ensure effective control of professional users. These products can only be used by trained and certified users, which means that the use of these products is at higher risk. The record book ensures that it is possible to trace where, when and what product was used, and to verify whether the product was used in accordance with the requirements.
- Support the correct and comprehensive implementation of Integrated Pest Management (IPM).
- Not all biocontrol substances are low-risk.

11. GRACE PERIOD FOR IMPLEMENTING MEASURES

A. Background

Grace periods as set out in implementing measures when an active substance approval is not-renewed or withdrawn serve the purpose of removing from the market products containing that active substance, while granting farmers additional time to use existing stocks of the product while they identify andimplement alternative pest control solutions In addition, grace periods allow time for Member States to assess applications and authorise alternative products not yet available in their territories, to replace the products being removed from the market..

More flexibility is granted in setting grace periods when reasons of withdrawal or non-renewal are not linked to concerns for human or animal health or to the environment.

Where reasonable alternatives do not exist, the maximum grace period is extended up to one year for sale and distribution, and two years for disposal, storage and use of existing stock of PPPs.

B. OPTIONS

Based on the above background, Member States are invited to express whether they:

Option 1: Support the Commission proposal; namely 6 months for sale and distribution, 1 year for disposal, storage, use of existing stock of PPPs. In case of no other alternative reasonable means, grace period is prolonged up to 1 year for sale and distribution, and up to 2 years for disposal, storage and use of existing stock of PPPs.

Option 2: In case of no other alternative reasonable means, 1 year for sale and distribution, 18 months for disposal, storage, use of existing stock of PPPs, for a total of 2.5 years of grace period.

12. BASIC SUBSTANCES

A. Background

The Commission proposal clarifies that only a basic substance may at a later stage be approved as an active substance, but not the other way around.

Some MS expressed concerns about the use of “stabilisers”, with the Commission clarifying that types and properties of substances that are allowed for these purposes will be included in the Guidance Document and furthermore in Implementing Acts.

The labelling of products containing basic substances that are already placed on the market for their primary intended purpose outside of plant protection cannot be mandatory as the manufacturer may not be aware of or may not wish and chose not to mention the possible

secondary use in plant protection of his product. However, specific provisions clarifying the labelling rules for products containing basic substances placed on the market specifically for plant protection will be established in the Implementing Act.

B. OPTIONS

Member States are invited to express whether they:

Option 1: support the Commission proposal

Option 2: want to propose an alternative (please specify).

13. MRLs Regulation – MRLs set a LOQ level

A. Background

The Commission proposal foresees that Article 14(2)(e) will be amended to set out that for substances that are not approved in the Union and that have certain particularly hazardous properties, the maximum residue levels (MRLs) that were set based on good agricultural practices in third countries or Codex maximum limits may be set at the limit of quantification (technical zero) if considered appropriate in the light of the outcome of an impact assessment.

As explained in the AGS meeting on 2 February 2026, the Vision for Agriculture and Food already announced an impact assessment (IA) of the proposal on competitiveness, trade and international obligations. In November 2025, the Commission launched a study preparing the IA. In the meantime, the Commission is proposing to already act on a case-by-case basis, while the IA is ongoing. The new MRLs for each hazardous substance will be prepared individually by means of a Commission Regulation which will be discussed (and approved by the MS by QMV) in the Standing Committee on Pesticides, Animals, Food and Feed (ScoPAFF), after consultation of third countries under the WTO/SPS procedure. They can be adopted by the Commission unless an objection is raised by either the Council or the Parliament as the procedure is the regulatory procedure with scrutiny.

B. OPTIONS

Based on the above background, Member States are invited to express whether they:

Option 1: support the Commission's proposal;

Option 2: keep the current MRL Regulation as it stands until the overall Impact Assessment is finalised.

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