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NOTE

From:	General Secretariat of the Council
To:	Delegations
No. Cion doc.:	17056/1/25 REV 1
Subject:	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 - Presidency compromise text

Delegations will find in the Annex the second Presidency compromise text in relation to the above proposal, limited to provisions regarding the Biocides Regulation (EU) No 528/2012 (recitals 34-35 and Article 4).

A new compromise text for provisions concerning Regulation 1107/2009 can be found in document 8691/26. Provisions related to MRLs (recital 27-33 and Article 3) and veterinary and food related issues ('cluster C', recitals 36-63 and Articles 5-11) are not covered by this text.

Additions to the Commission proposal are indicated in **bold**, deletions are marked as ~~strikethrough~~. Changes compared to the first compromise text (set out in WK 4320/2026) are indicated in **bold underlined** or ~~strikethrough underlined~~.

ANNEX

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

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[…]

(34) Regulation (EU) No 528/2012[1] sets out the procedures for approval of biocidal active substances and authorisation and making available on the market and use of biocidal products. The completion of the review programme of existing biocidal active substances set out in Article 89 of that Regulation is significantly delayed. In order to ensure that Member States can dedicate their resources to the completion of the review programme, it is appropriate to set an unlimited duration for the approval of active substances , except for active substances meeting exclusion or substitution criteria under Articles 5(1) or 10**(1)** of that Regulation as those have properties that are of concern to human or animal health or the environment, and except for active substances for which time limits of approvals are considered necessary in the light of the outcome of the risk assessment conducted prior to a decision on an approval. The approval of active substances already approved should be converted into unlimited approvals following these new rules, except for active substances identified as meeting exclusion or substitution criteria under Articles 5(1) or 10**(1)** of that Regulation, active substances for which the renewal examination already started for which the renewal evaluation should continue or for which the approval should expire when no application for renewal was submitted by the deadline. A possibility should be foreseen that the Commission periodically selects a number of active substances based on specific criteria

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1 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, pp. 1–123, ELI: http://data.europa.eu/eli/reg/2012/528/oj)

for which a renewal procedure should be triggered, while also maintaining the possibility to initiate early reviews pursuant to Article 15 of Regulation (EU) No 528/2012. Criteria for the selection of active substances subject to the renewal procedure should include, among others, relevant new or updated data requirements or guidance documents, **including on endocrine-disrupting properties,** indications of safety concerns for human or animal health or the environment, **including environmental surveillance alerts**, new scientific or technical knowledge and available monitoring data, and might take into account requests from Member States. **The selective renewal assessment should be conducted on the basis of a dedicated regularly published ~~calendar of~~ work programme. This ~~calendar of~~ work programme should include a calendar of work and be discussed with the experts of Member State competent authorities in the Commission expert group of the 'Competent Authorities for Biocidal Products'. Furthermore, the Commission should provide a mandate to the Agency to periodically perform a literature review relating to risks of active substances and to advise on the planning of the calendar of work.**

(35) To simplify and accelerate the procedure for adoption and publication of the decisions on applications for Union authorisation of biocidal products submitted pursuant to Chapter VIII of Regulation (EU) No 528/2012, the individual decisions should no longer take the form of Commission Implementing Regulations and be published at the EU Official Journal, but should take the form of Commission Implementing Decisions to be notified to the applicants, and only summaries of those Decisions should be published at the EU Official Journal for transparency.

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Article 4

Amendments to Regulation (EU) No 528/2012

Regulation (EU) No 528/2012 is amended as follows:

(1) in Article 4, paragraph 1 is replaced by the following:

> '1. An active substance shall be approved if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in Article 19(1), point (b), taking into account the factors set out in Article 19(2) and (5).
>
> Approvals shall be for an unlimited time except for active substances that are identified as candidates for substitution in accordance with Article 10 or where the conditions of approval, for duly justified reasons, specify the expiry date of the approval in accordance with paragraph 3 of this Article. An active substance that falls under Article 5 may only be approved for an initial period not exceeding five years.';

(2) in Article 4, paragraph 3, point (h) is replaced by the following:

> '(h) the date of approval and, when appropriate, the expiry date of the approval of the active substance.' ;

(3) in Article 9, paragraph (1), point (a) is replaced by the following:

> '(a) adopt an implementing Regulation providing that an active substance is approved, and under which conditions, including the date of approval and, when appropriate, date of expiry of the approval; or';

(4) In Article 10, paragraph (4) is replaced by the following:

> 'The approval of an active substance that is considered as a candidate for substitution and each renewal shall be for a period not exceeding seven years.';

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(5) In Article 12, paragraph (3) is replaced by the following:

'3. The renewal of an approval of an active substance shall be for an unlimited time for all product-types to which the approval applies, unless the active substance is identified as a candidate for substitution in accordance with Article 10 or a shorter period is specified in the implementing act adopted in accordance with Article 14(4), point (a), renewing such an approval.';

(6) in Article 13, paragraph 1 is replaced by the following:

'1. Applicants wishing to seek renewal of the approval of an active substance, which is subject to a specified expiry date for one or more product-types, shall submit an application to the Agency at least 550 days before the expiry of the approval. Where there are different expiry dates for different product-types, the application shall be submitted at least 550 days before the earliest expiry date.';

(7) a new Article 14a is inserted:

'*Article 14a*

Renewal of an active substance with unlimited approval

1. The Commission may adopt implementing acts, in accordance with the examination procedure referred to in Article 82(3) identifying active substances with unlimited approval for which a renewal procedure shall be conducted. The implementing acts shall list the active substances and product-types concerned, and set the expiry date of their current approvals that allows for an evaluation of the applications and the adoption of a decision on the renewal of approval.

Article 13 and Article 14 apply *mutatis mutandis* for the submission, acceptance and evaluation of the applications.

2. The identification of the active substances concerned shall take into account, among others, relevant new or updated data requirements or guidance documents, indications of safety concerns for human or animal health or the environment, new scientific or technical knowledge and available monitoring data, and may take into account requests from Member States.';

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(8) a new Article 15a is inserted:

'*Article 15a*

Approval periods of active substances approved by *[OP, please insert the date: date of the entry into force of this Regulation]*

For all active substances approved under Regulation (EU) No 528/2012 at the latest on *[OP, please insert the date: date of the entry into force of this Regulation]* for one or more product-types, approvals shall be deemed unlimited in time for the concerned product-types, except for:

(a) active substances identified as meeting the criteria set out in Article 5(1) or Article 10**(1)**;

(b) active substances for which an application for renewal was submitted by the deadline set out in Article 13(1) by *[OP, please insert the date: date of the entry into force of this Regulation]*;

(c) active substances for which no application for renewal was submitted by the deadline set out in Article 13(1) by *[OP, please insert the date: date of the entry into force of this Regulation].';*

(9) In Article 44, paragraph (5) is replaced by the following:

'5. Upon receipt of the opinion of the Agency, the Commission shall adopt either an implementing act granting the Union authorisation of the biocidal product or an implementing act stating that the Union authorisation of the biocidal product has not been granted. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Summaries of Commission decisions shall be published in the Official Journal of the European Union, indicating the decision number, the nature of the decision, the name of the biocidal product, the active substances contained in the biocidal product, the product-types, the authorisation number, the authorisation holder, and the expiry date of the authorisation.

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The Commission shall, at the request of a Member State, decide to adjust certain conditions of a Union authorisation specifically for the territory of that Member State or decide that a Union authorisation shall not apply in the territory of that Member State, provided that such a request can be justified on one or more of the grounds referred to in Article 37(1).';

(10) In Article 46, paragraph (4), the first subparagraph is replaced by the following:

'Upon receipt of the opinion of the Agency, the Commission shall adopt an implementing act renewing the Union authorisation or refusing to renew the Union authorisation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).'.

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