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NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	9005/26
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 (BPR)

Delegations will find in the Annex the third 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).

Additions to the Commission proposal are indicated in **bold**, deletions are marked as ~~strikethrough~~. Changes compared to the second compromise text are indicated in **bold underlined** or ~~strikethrough underlined~~.

Based on the discussions in the previous AGS meetings and the comments received in writing, the Presidency is proposing as the main change to maintain the current principle of approvals for active substances with an expiry date, while prolonging the duration of the approval period, and to introduce a temporary suspension of renewals of approvals until the end of the work programme.

This proposal strikes the balance between simplification and protection of human or animal health or the environment. It is based on the rationale to alleviate the back lock accumulated in the completion of the review programme, while taking into account concerns to human or animal health or the environment that would require a reniewed examination of active substances.

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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 a~~n unlimited~~ **longer** duration **of 20 years** 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 **shorter** 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 **also** be converted into ~~unlimited~~ approvals **of a longer duration (30 years)** ~~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~~

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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)

~~Commission periodically selects a number of active substances based on specific criteria 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 in particular 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 work programme. This 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.~~**

(34a) Furthermore, to avoid the accumulation of delays in renewal procedures which are to be launched before the finalisation of the review programme referred to in Article 89 of Regulation (EU) 528/2012, the obligation to apply for a renewal should be temporarily suspended until the finalisation of the work programme. The Commission should be empowered to adopt implementing acts to modify the expiry date of active substances approved from [date of adoption of this Regulation] until the finalisation of the work programme, to ensure that upon the finalisation of the work programe the renewal of active substance will be decalated in time and avoid the creation of additional delays.

(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.

[…]

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 **granted** for ~~an unlimited time~~ **20 years** 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 **granted** for ~~an unlimited time~~ **30 years** 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**, the following paragrahs are inserted** ~~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.~~

1a. By way of derogation from paragraph 1, the obligation to submit an application for renewal shall be temporarily suspended from [OP: please insert the date = date of entry into force of this Regulation] until the completion of the work programme referred to in Article 89(1), except for active substances that are identified as meeting the criteria set out in Article 5(1) or Article 10(1).

1b. For active substances for which the obligation to submit an application is temporarily suspended in accordance with paragraph 1a, the Commission shall, by means of implementing acts, postpone the initial expiry date of approval, for the concerned product-types. The period of extension shall be calculated to amount to the time between [OP: please insert the date= date of entry into force of this Regulation] and the date set out for the achievement of the work programme set out in Article 89(1). Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).';

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~~(7) a new Article 14a is inserted:~~

~~'*Article 14a*~~

~~Renewal of approval 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,~~ **~~in particular on endocrine-disrupting properties,~~** ~~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.';~~

(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~~ **granted** ~~unlimited~~ **for 20 years** ~~in time~~ for the concerned product-types, except for:

(a) active substances identified as meeting the **exclusion or substitution** 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.

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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