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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 MRLs, Regulation (EC) No 396/2005 (recitals 27-33 and Article 3).

Provisions related to Regulation 1107/2009, Regulation (EU) No 528/2012 and veterinary and food related issues (‘cluster C’) are not covered by this text.

Additions to the Commission proposal are indicated in **bold**, deletions are marked as ~~strikethrough~~.

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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[…]

(27) Regulation (EC) No 396/2005[1] sets the procedure for defining maximum residue levels ("MRLs") of pesticides in or on food and feed of plant and animal origin. In the Vision for Agriculture and Food, the Commission announced it would pursue a stronger alignment of production standards applied to imported products, notably on pesticides and establish the principle, in compliance with the EU's international obligations, that the most hazardous pesticides banned in the EU for health and environmental reasons should not be allowed back to the EU through imported products. To advance on this, the Commission has launched in November 2025 a study to prepare an impact assessment that will consider the impacts on the EU's competitive position and the international implications and, if appropriate, propose amendments to the legal framework. In the meantime **the procedure for setting out MRLs in** Regulation (EC) No 396/2005 should already be amended to provide that, for substances that are not approved in the Union and that have certain particularly hazardous properties, **have negative effects on honeybees or accumulate in unacceptable levels in groundwater,** MRLs that have been set based on good agricultural practices in third countries or Codex maximum limits ~~may be~~ **should be** set at the limit of quantification (technical zero), **if appropriate based on a prior impact assessment.**

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[1] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, pp. 1–16, ELI: http://data.europa.eu/eli/reg/2005/396/oj)

~~(28) This concerns substances with mutagenic, carcinogenic or reprotoxic properties as well as endocrine disruptors that may cause adverse effects in humans. Therefore, no level of residues leading to exposure of consumers should be allowed in order to ensure a high level of protection for consumers in the Union.~~

(29) ~~In addition~~, **This concerns substances with mutagenic, carcinogenic or reprotoxic properties as well as endocrine disruptors that may cause adverse effects in humans** and substances that are persistent organic pollutants (POP), persistent, bioaccumulative and toxic (PBT) substances, and very persistent and very bioaccumulative (vPvB) substances, as well as substances with endocrine disrupting properties that may cause adverse effect in non-target organisms. Persistent substances, by their very nature, resist degradation, resulting in prolonged presence in the environment. Their accumulation poses a significant threat to ecosystems, endangering biodiversity, agricultural production and food security. Endocrine disruptors, similarly, interfere with the hormonal systems of living organisms, causing detrimental effects not only to individual species, including migratory species, but also to entire ecosystems across national boundaries. Therefore, these substances create environmental concerns of a global nature that have a connection with the territory of the Union. **In addition, this concerns active substances which have unacceptable effects on honeybees or on the survival or development of their colonies, given the growing worldwide concern that the decline of pollinators is a serious threat to global biodiversity, the environment and sustainable development, as well as to maintaining agricultural productivity and food security. Furthermore, it concerns active substance for which normal conditions of use would lead to a concentration of the active substance or of metabolites, degradation or reaction products in groundwater at a level not complying with the approval criteria for active substances. Groundwater is a valuable but limited natural resource and its conservation is equally a global concern. For coherence reasons and not to undermine the efforts already untertaken in the Union to ensure a high level of protection of human health and the environment, it is important to have a stringent approach towards their residues in imported products, in compliance with international obligations.** ~~Not allowing residues of these substances in food in the~~

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~~Union aligns with international efforts to combat pollution and supports global initiatives aimed at sustainable development and biodiversity conservation[2].~~

(29b) For residues of such active substances, the Commission should systematically assess existing MRLs set out in accordance with Codex Alimentarium (CLX) or GAP in a third country. Based on the outcome of a prior impact assessment, the Commission, should, as appropriate, lower them or set new MRLs.

(29c) To allow for the continued and effective use of plant protection products under the derogation set out in Article 4(7) of Regulation (EC) 1107/2009, MRLs related to uses relying on such a derogation should remain in place despite the properties of the active substance.

(30) ~~Where an appropriate evaluation by the Authority of the hazardous properties of the substance under Regulation (EC) No 1107/2009 is not available, the Commission should ask the Authority for an evaluation under Article 43 of Regulation (EC) No 396/2005. Furthermore,~~ ~~the~~ **The** term "import tolerance" is often misunderstood. Therefore, **to simplify Regulation (EC) No 396/2005,** the term "import tolerance" **which refers to an MRL based on good agricultural practices (GAP) in a third country** should **no longer** be ~~repealed~~ **used** and it should be clarified that ~~the definition of~~ ~~good agricultural practice~~ **an MRL can be based** ~~applies equally to the Union and to a third country for the setting of MRLs~~ **either on a GAP in the EU or on a GAP in a third country**.

(31) **In addition, when** lowering MRLs under Regulation (EC) No 396/2005, a reasonable period should be allowed to elapse before the new MRLs become applicable, in order to permit Member States, third countries and food business operators to adapt themselves to the new requirements. It is recognised that fresh products, being perishable, are typically sold and consumed prior to the date of applicability of new MRLs. However, products with extended shelf lives, often processed, may still be on the market when the new lower MRLs become effective. To ensure legal certainty and to prevent unnecessary economic losses for farmers and food business operators, as well as to prevent food waste, it is deemed proportionate that products lawfully placed on the market in the Union before the applicable date of the new

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[2] Stockholm Convention on Persistent Organic Pollutants (POPs), https://www.pops.int/; Convention on Biological Diversity, https://www.cbd.int/

measure, and compliant with the MRLs valid at the time of their placing on the market in the Union, should be permitted to remain on the market unless food safety is compromised. **Such transitional arrangements should equally apply to products under storage in a third country for the purpose of sale on the Union market, including offering for sale or any other form of transfer, to avoid a discriminatory treatment between imported and domestic products.**

[…] no changes to recitals 32 and 33

Article 3

Amendments to Regulation (EC) No 396/2005

Regulation (EC) No 396/2005 is amended as follows:

[…] no changes to points 1-3

(4) Article 14 is amended as follows:

(a) ~~In paragraph (2),~~ a new subparagraph **(2a)** is **inserted** ~~added~~:

'By way of derogation from **paragraph 2**, point (e), where the active substance has one or more of the properties set out in points 3.6.2 to 3.6.5, 3.7.1 to 3.7.3, and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 **or does not meet criteria 3.8.3 or 3.10 of that Annex,** in accordance with the latest available evaluation under Regulation (EC) No 1107/2009 or a specific evaluation in accordance with Article 43 ~~of Regulation (EC) No 396/2005~~ **this Regulation**, a MRL ~~has been set based on a CXL or a GAP implemented in a third country can be revoked and~~ **shall be** set in accordance with Article 18(1)(b) or Article 16 **of this Regulation** ~~if considered appropriate in the light of the outcome of an~~ **based on a prior** impact assessment.

The Commission shall submit to the Committee referred to in Article 45(1) the draft Regulation and the results of the impact assessment without delay and at the latest within six months after:

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(i) an evaluation under Article 43 of this Regulation establishes that the substance meets one or more of the properties referred to in the first subparagraph; or

(ii) the expiry of the maximum grace period established at the adoption of a Regulation under Regulation (EC) No 1107/2009 non-approving, non-renewing or withdrawing the approval of an active substance meeting one or more of the properties referred to in the first subparagraph.

This paragraph shall not apply for MRLs applicable to products on which uses of plant protection products containing the active substance are authorised in the Union in accordance with the derogation set out in Article 4(7) of Regulation (EC) No 1107/2009.';

(b) A new paragraph **2b** is inserted:

'**2b**. Where it is necessary in order to allow for the normal marketing, processing and consumption of products, the regulations setting or modifying MRLs provided for in Article 14 may establish transitional measures allowing for the placing or remaining on the market in the Union of products that, at the time of their placing on the market or at the time of their placing into storage after production, **including storage in a third country for the purpose of sale on the Union market**, were compliant with the MRLs applicable or to which no MRL was applicable.

The burden of proving when the products were placed on the market or placed into storage after production shall be borne by the food business operator.

[…] no changes to points 5-6

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