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LIMITE

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus X Food and feed safety: MS comments - Follow-up of the AGS of 29 May 2026

Delegations will find enclosed comments regarding the Omnibus X, Food and feed safety, as received from ther following Member States: BE, CZ, DK, DE, EE, ES, FR, IT, LU, HU,NL, AT, PL, SK, FI.

Omnibus X – Food and feed – Regulation on simplification and strengthening of food and feed safety requirements

– MS comments –

DDL 03/06/26 12:00, MS comments AGS 29/05/2026

Table of Contents

BELGIUM 2

CZECHIA 3

DENMARK 5

GERMANY 7

ESTONIA 9

SPAIN 11

FRANCE 13

ITALY 49

LUXEMBOURG 51

HUNGARY 52

NETHERLANDS 53

AUSTRIA 57

POLAND 60

SLOVAKIA 63

FINLAND 66

BELGIUM

BELGIQUE/BELGIË

Belgium generally welcomes the latest compromise text on Omnibus X – Food & Feed.

Belgian Deputy Prime Minister and Minister of Foreign Affairs, Maxime Prévot, together with Deputy Prime Minister and Minister of Public Health Frank Vandenbroucke and Jean-Luc Crucke, Minister of Climate, will shortly address a letter to their CY homologues to express the grave concerns with the initial Commission proposal on notably unlimited approval, and to share their positive assessment of your proposed compromise.

We would propose one element for further improvement, which is to align the BPR approval periods proposed by the Presidency, namely 20 years for the initial approval and 30 years for renewals with the approval periods such as proposed by the Presidency in PPP. This will improve consistency and will bring simplification to enterprises and administrations alike.

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CZECHIA

ČESKO

Regulation 1107/2009

The Czech Republic commends the work of the Presidency and its efforts to draft the text of several articles of **Regulation 1107/2009** in a way that reduces the administrative burden and facilitates the placing of low-risk substances on the market. We believe that if Member States were given more space for the technical assessment of the proposed changes, we could achieve a more ambitious and balanced solution to the current difficulties faced by Member States and, ultimately, the Commission in the evaluation of active substances and the authorization of plant protection products.

Based on long-term experience, the Czech Republic supports in particular the amendment to **Article 4(7):**

We consider it essential to maintain the wording of this article in a form that allows for a realistic solution to situations where sufficient alternatives are not available, thereby preventing disproportionate impacts on agricultural practices. We consider further amendments to the article to be unacceptable.

The reasoning:

The article should largely serve to compensate for the failure to secure the option of approving or retaining substances based on a socioeconomic analysis, as well as the failure to secure amendments to Article 53 that would have allowed Member States to have more products available in the event of emergencies in plant protection.

If the loss of active substances is not because the applicant is no longer supporting it on the market, then it is because they meet the cut-off criteria.

Among the cut-off criteria, endocrine disruption (ED) is the most common reason for not approving active substances.

Therefore, if we include ED as another cut-off criterion in Article 4(7), we will significantly limit the possibility of using substances for essential plant protection applications, thereby completely negating the rationale behind the Commission's proposed amendment to Article 4(7).

The current wording of Article 4(7) is less restrictive than it would be with the amendment of ED. To date, this article has not been used, and its potential future use will be completely blocked.

Articles 5 and 14: Approval period for active substances: The Czech Republic advocates for a minimum approval period of 20 years; at the same time, we are open to discussing a compromise on a longer timeframe if there is sufficient support for this approach during the negotiations.

The reasoning:

The currently proposed extension of the approval period (15 years for initial approval, 20 years for renewal) and the renewal of active substance approvals effectively reflect the current situation and therefore do not constitute a rationalization of the entire evaluation system.

Article 3 (34): Biostimulants

As for the definition of biostimulants, we prefer the Commission's original proposal. We disagree with the amendment included in the current compromise proposal and will not support it.

The reasoning:

The new compromise text proposed by the Presidency complicates the definition. If the proposed wording were maintained, in our view it would significantly disrupt the existing regulatory

framework for plant biostimulants established by the Fertilizing Products Regulation (EU) 2019/1009, which is not the subject of Omnibus X.

The proposed changes introduce vague scientific terms related to plant hormonal regulation (such as "interference with endogenous plant hormonal signalling pathways"), which does not align with current scientific understanding, where physiological processes are interconnected. In practice, this could lead to even common plant biostimulants or nutrients being classified as plant protection products. This would require individual assessment of each product, increase the administrative burden, and risk differing interpretations among Member States. The result would be uncertainty for both manufacturers and farmers and the potential withdrawal of already available products from the market. The proposal would thus contradict the Omnibus X objective of simplifying legislation.

Regulation 396/2005

With regard to **Regulation 396/2005**, the Czech Republic also appreciates the Presidency's efforts to find a compromise.

Article 14: The Czech Republic continues to support maintaining the current legislative framework until the Commission completes its comprehensive impact assessment.

Following the discussion at the CRP II meeting on May 27, 2026, during which ten Member States expressed reservations regarding the Presidency's proposal, the Czech Republic calls on the Presidency to incorporate into the proposal a requirement for a comprehensive impact assessment of the proposed amendments and to postpone changes to the current framework until further information becomes available.

The reasoning:

Even in the context of the broader debate on the proposed changes, the Czech Republic insists on completing the impact assessment before adopting fundamental systemic changes. Without a proper impact assessment, it is not possible to make a responsible decision on changes that may have significant consequences for the agri-food sector, trade, and the EU's competitiveness.

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DENMARK

DANMARK

Regulation (EC) No 1107/2009:

Denmark welcomes the compromise proposal from the Presidency that unlimited approvals/authorisations will only apply to low-risk active substances and for products containing them. This is a major change, so thank you for listening to our concerns. We can support this proposal.

The compromise text suggests to extend the approval periods for active substances which are not low-risk. We can support this proposal. However, it should be explicitly mentioned in article 14 that the approval period for candidates for substitution will still be 7 years.

Denmark cannot support the wording in the compromise text in article 4(7), and this is a red line for us. Current wording means that active substances with proven unacceptable risk to human health and environment can be approved for five years, and this is still the case with the compromise proposal. This will seriously affect the level of protection. Our suggestion for wording which we can accept is:

By way of derogation from paragraph 1, where on the basis of documented evidence (i) included in the application or, (ii) provided upon request of the Commission, the Authority or the rapporteur Member State by the applicant in the course of the approval or renewal procedure or, (iii) submitted by one or more Member States in the course of the approval or renewal procedure, an active substance is necessary to control a serious danger to plant health or plant production which cannot be contained by other reasonable means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years, even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.

The evidence referred to in the first subparagraph shall be submitted during the approval process, by the applicant or the Member States and, where relevant, supported by official or scientific bodies involved in agricultural activities.

The derogation provided for in the first subparagraph shall not apply to active substances which are or have to be classified in accordance with Regulation (EC) No 1272/2008, as endocrine disrupters category 1 (without a threshold), mutagenic category 1A or 1B, carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A or persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), or that are a persistent organic pollutant (POP) according to the criteria set out in point 3.7.1 of Annex II.

Member States may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control the serious danger to plant health or plant production in their territory identified pursuant to the first subparagraph.

At the same time, they shall draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods.

We are still very critical about the extension of the grace period from 18 months to three years.

We support the revised definition of biocontrol substances so that substances originating from living organisms or derived by biological processes must also meet the low-risk criteria. We also support that only low-risk biocontrol will benefit from the advantages during product authorization.

Regulation (EC) No 528/2012:

Denmark welcomes the compromise proposal from the Presidency where the current principle for renewals of biocidal active substances is maintained. This is a major change, so thank you for listening to our concerns. We can support this proposal.

However, we find that the proposed lengths of the approval periods are too long. Quite a scientific development may happen within 30 years. The proposed very long approval periods would possibly lead to an increased need for use of early reviews af active substances (article 15), which is financed by the member states and not the applicants. We can support an extension of the approval periods; however, we would support approval periods for first approvals of 15 years and renewal periods of 20 years in line with the proposed lengths in regulation 1107/2009 as suggested by others at the AGS-meeting on 29 May.

Further, we support the proposal of prolongating the existing approvals until the completion of the work program. However, we find it important that this is done in a way, where the existing approvals are not all prolonged to the same date in order to avoid a backlog of renewal applications to be assessed in parallel. This could be mitigated by prolonging the existing affecting approvals, except for active substances that are identified as meeting the criteria set out in Article 5(1) or Article 10(1), to 15 years, a period similar to the proposed approval length for future first approvals. This would spread out the coming renewal applications over time.

Comments from Denmark regarding the German proposal to compromise text Omnibus X (Food and feed safety):

Amendments to Article 3 (4) of EU Commission proposal (17056/1/25) - focused on proposed new subparagraph in Article 14 (2) of Regulation (EC) No 396/2005

Denmark shares the concern regarding the potential consequences of major changes to the current procedure in regulation (EC) No 396/2005 relating to import tolerances and Codex limits. We find it essential that the conclusions from the general impact assessment are available before any significant amendments to article 14 in regulation 396/2005 are adopted.

We find it important that criteria listed in paragraph 2 are clearly defined for the impact assessment. A clear list of criteria should clarify every aspect of the MRL revision and contribute to a more transparent decision-making process. Furthermore, it is important that the MRL is not lowered to technical zero before the specific impact assessment has been conducted.

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GERMANY

DEUTSCHLAND

German comments following COREPER on 27 May 2026
Amendments to proposed new subparagraph in Article 14 (2) of Regulation (EC) No 396/2005
(based on latest Presidency proposal; **German** additions in **bold,** deletions in ~~**bold**~~)
…(4) Article 14 is amended as follows:

(a) A new ~~**sub**~~paragraph **(**2a**)** is inserted:

‘2a. 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 this Regulation, a MRL **that has been set based on a CXL or a GAP implemented in a third country can be reviewed and** ~~**shall be**~~ set in accordance with Article 18(1)(b) or Article 16 of this Regulation if considered appropriate based on a prior impact assessment. **The impact assessment shall take into account especially the following criteria**:

- **a risk assessment carried out by the Authority,**
- **compatibility with WTO and SPS requirements,**
- **the impact on EU Member States as well as on third countries,**
- **the needs of the entire food and feed chain.**

~~**The Commission shall submit to the Committee referred to in Article 45(1) the results of the impact assessment and, where appropriate, the draft Regulation, without delay and at the latest within six months after:**~~
~~**(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 added:
‘2b. The provisions in Article 14 (2a) will be reviewed as soon as the general impact assessment initiated under the Vision for Agriculture and Food is available.‘

(~~**b**~~**c**) A new paragraph 2~~**a**~~**c** is inserted:
‘2~~**a**~~**c**. (…)‘

Respective recitals also need to be amended accordingly (additions in **bold,** deletions in ~~**bold**~~):

‘(27) Regulation (EC) No 396/2005 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) **or at a higher limit**, ~~**if appropriate**~~ **based on a prior impact assessment. The impact assessment should follow specific criteria taking into account especially a risk assessment carried out by the Authority whether safe MRLs (CXL or GAP) could be derived, compatibility with WTO and SPS requirements, the impact on EU Member States as well as on third countries, and the needs of the entire food and feed chain.**

Since this amendment to Article 14 of Regulation (EC) No 396/2005 is considered as interim approach, the provisions should be reviewed and amended not later than six months after the results of the aforementioned impact assessment initiated under the Vision for Agriculture and Food are available.‘

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ESTONIA

EESTI

Therefore we would like to underline that Estonia have **2 red lines** conserning the Food and Feed Omnibus X proposal, both on the cluster B: Regulation (EC) No 1107/2009 and Regulation (EC) 396/2005.

In the context of Cluster B of **Regulation (EC) No 1107/2009**, the following issues constitute red lines for us.

First, regarding Article 4(7), we consider it essential to take socio-economic impacts into account in cases where no alternatives are available, including impacts on farmers, food production and the competitiveness of the sector.

Second, Estonia considers it important to maintain the unlimited validity of approvals for active substances and authorisations for plant protection products under Article 5 and related provisions. We support the European Commission's original proposal and consider that the Presidency's amendment would constitute a step backwards towards a time-based reassessment system.

In the context of **Regulation (EC) No 396/2005**, Estonia supports status quo, we are strongly in position that this is a substantive change and not technical, and therefore Estonia is in the position that Regulation needs more deeper discussion on expert level taking into account the outcome of the impact assessment. Additionally, we foresee the increase of the administrative burden for all parties, which should be avoided and we cannot support of that.

In the mind of compromise we may support the Commission original proposal, in the terms that the outcome of the impact assessment shall be taken into account before any changes are made.

Estonia has studied carefully the proposal on the MRLs from Germany and we could support their proposal if Presidency is willing to taking it on the board.
Germany´s proposal on MRLs what we can agree with is as following:
Amendments to proposed new subparagraph in Article 14 (2) of Regulation (EC) No 396/2005 (based on latest Presidency proposal; **German** additions in **bold,** deletions in **bold**)

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…(4) Article 14 is amended as follows:

(a) A new **sub**paragraph **(**2a**)** is inserted:

'2a. 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 this Regulation, a MRL **that has been set based on a CXL or a GAP implemented in a third country can be reviewed and shall be** set in accordance with Article 18(1)(b) or Article 16 of this Regulation if considered appropriate based on a prior impact assessment. **The impact assessment shall take into account especially the following criteria**:

- **a risk assessment carried out by the Authority,**
- **compatibility with WTO and SPS requirements,**
- **the impact on EU Member States as well as on third countries,**

- **the needs of the entire food and feed chain.**

The Commission shall submit to the Committee referred to in Article 45(1) the results of the impact assessment and, where appropriate, the draft Regulation, without delay and at the latest within six months after:
(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 added:
'2b. The provisions in Article 14 (2a) will be reviewed as soon as the general impact assessment initiated under the Vision for Agriculture and Food is available.'
(b**c**) A new paragraph 2a**c** is inserted:
'2a**c**. (…)'

Respective recitals also need to be amended accordingly (additions in **bold,** deletions in **bold**):

'(27) Regulation (EC) No 396/2005 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) **or at a higher limit**, **if appropriate based on a prior impact assessment. The impact assessment should follow specific criteria taking into account especially a risk assessment carried out by the Authority whether safe MRLs (CXL or GAP) could be derived, compatibility with WTO and SPS requirements, the impact on EU Member States as well as on third countries, and the needs of the entire food and feed chain.**

Since this amendment to Article 14 of Regulation (EC) No 396/2005 is considered as interim approach, the provisions should be reviewed and amended not later than six months after the results of the aforementioned impact assessment initiated under the Vision for Agriculture and Food are available.'

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SPAIN

ESPAÑA

As a general comment, a transitional period should be established for the whole Regulation not only for the deadlines for substances, as the working system would have to be adapted to the new scheme.
On the other hand, a prioritisation procedure is proposed in the approval of biocontrol active substances, as well as plant protection products containing low-risk active substances, which enters into force automatically, but the workload for the Member States remains intact, if not increasing. Therefore, a transitional period for amendments to the Regulation of at least 2 years should be provided for. This request has been expressed on several occasions without having obtained any change in the text in this regard.
We want to highlight that in our view, the Commission's proposal has been carried out without any consensus with the Member States, and that is why we believe that many of the aspects included in it are difficult to achieve, and will generate legal uncertainty.
It would be highly recommended to be able to discuss the proposal in the Council working groups.
The critical points of the proposal, which should be red lines for Spain, are considered as follows:

1. Article 3.35: Definition of active substance for biocontrol and advantages that would be granted to the products containing them. We advocate the prioritization of innovation, but not limeted to biocontrol active substances. Our farmers must have the most innovative, sustainable and truly effective phytosanitary tools in the shortest possible time. However, the proposal focuses on the approval of biocontrol active substances, when it has already been demonstrated that these substances are not always low-risk or in many cases effective. Therefore, new solutions should be prioritised, regardless of whether their origin is biological or not. As regards the definition of biocontrol, it should be drafted in such a way that all substances included in the definition are low-risk, not only those contained in the new paragraph d, or delink it from the low-risk criterion, and that the benefits come retrospectively in the product authorisation process, and only in the case that all active substances are low-risk. In addition, we consider that prioritising biocontrol/low-risk solutions in this way could lead us to not have 'traditional' phytosanitary tools, which are necessary as a last resort in integrated pest management.

2. Article 37(5) and Article 42(3): The so-called "tacit agreement" in mutual recognitions for products with low-risk active substances or biocontrol active substances should be eliminated, as it creates legal uncertainty. The obligation now to process the authorisation without being able to review the procedure at national level entails an additional workload, which is difficult to understand in a simplification process. It is emphasized that our Law 43/2002 on Plant Health establishes that plant protection products may only be placed on the market if they have previously been authorized by the Ministry of Agriculture, Fisheries and Food and registered in the Official Register of Phytosanitary Products and Material. Any renewal, extension of uses and any other modification of authorisations, as well as their extinction, shall also be authorised and entered in the register. It is therefore not compatible with the national legislative framework.

3. Articles 14(2) and 18a (active substances), 32(1) and 43a (products): The alleged unloading of work that would entail the unlimited approval of low-risk active substances, and the exemptiom to review the authorisations of products containing them, is called into question, since very few active substances are approved lately without data gaps, critical areas of concern or other uncertainties, which means that in practice few active substances can be approved unlimitedly. In addition to the above, more work is

generated with the new Article 18a, and the targeted reassessment of the active substances that are decided, as well as the review of the products that contain them. With the current system of review of active substances and products, the workload is defined, as well as the times when such work is expected. However, the work generated by the targeted reassessment of Article 18a is unclear, including the times and additional workload it will entail, so we cannot ensure that we are able to assimilate this new workload. From the point of view of the Spanish position, this aspect is key to calling into question the alleged simplification of the proposal.

4. Article 59(6)a and (b): As far as data protection is concerned, we believe that it will greatly discourage innovation on the part of companies by not seeing their rights protected and will put an additional workload on Member States that will have to dump the information on the future European platform within a maximum period of 3 months. This new task reinforces the idea that the proposal is not geared towards simplification, but has created new burdens and tasks for Member States.

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FRANCE

France

AGRAP/2026/472 Paris, le 28 mai 2026

Objet : Réponse à l'appel à commentaires de la Présidence sur le cluster C de l'omnibus concernant la simplification et le renforcement des exigences en matière de sécurité des denrées alimentaires et des aliments pour animaux.

Les autorités françaises souhaitent faire part des commentaires suivants sur le cluster C (sujets vétérinaires et alimentaires) de l'omnibus concernant la simplification et le renforcement des exigences en matière de sécurité des denrées alimentaires et des aliments pour animaux.

S'agissant de la proposition de compromis de la présidence sur le règlement 2017/625 relatif aux contrôles officiels

Les autorités françaises ont toujours utilisé les DSCE-PP concernant les contrôles des végétaux et produits végétaux (VPV) couverts par l'article 73 et des matériaux d'emballage en bois.
Selon l'interprétation des autorités françaises de la réglementation, rien ne s'oppose à l'utilisation des DSCE-PP pour ces contrôles, considérant notamment que ces contrôles sont clairement prévus par la réglementation de l'UE. Les autorités françaises rejoignent la position de l'Italie et ne considèrent pas que l'utilisation du DSCE-PP dans ce cadre affaiblit le règlement sur les contrôles officiels.
Elles rappellent également que la Commission a créé la NOA afin que les Etats membres n'utilisent pas à tort les DSCE-D lors des contrôles qu'ils effectuent sur la base de leur réglementation nationale - il n'était pas question à cette occasion du sujet des contrôles des VPV articles 73 et des matériaux d'emballage en bois.
L'utilisation du NOA sous-entend, du point de vue des autorités françaises, que ces envois relèvent des art. 44 et 45 RCO, ce qui impliquerait 100% de pré-notifications et 100% de contrôles documentaires : ce dispositif ferait peser des charges administratives et techniques disproportionnées tant aux opérateurs qu'aux autorités de contrôle.
Les autorités françaises restent favorables aux ajouts proposés aux articles 56 et 57 dans le document de discussion du groupe du 22 mai 2026, dans la mesure où il s'agit d'une faculté laisser aux Etats membres.

Courtesy translation:
Regarding the Presidency's compromise proposal on Regulation 2017/625 on official controls:
The French authorities have always used CHED-PPs for controls on plants and plant products (PPP) covered by Article 73 and on wood packaging material.
According to the French authorities' interpretation of the regulations, nothing prevents the use of CHED-PPs for these controls, considering in particular that these controls are clearly provided for by EU regulations. The French authorities align with Italy's position and do not consider that using the CHED-PP in this context weakens the Official Controls Regulation (OCR).
They also recall that the Commission created the NOA (Official Notification of Arrival) to prevent Member States from mistakenly using CHED-Ds during controls carried out on the basis of their national regulations — the issue of controls on Article 73 plants and plant products and wood packaging material was not raised on that occasion.
From the French authorities' point of view, using the NOA implies that these consignments fall under Articles 44 and 45 of the OCR, which would require 100% pre-notifications and 100% documentary checks: such a mechanism would impose disproportionate administrative and technical burdens on both operators and control authorities.

The French authorities remain in favor of the proposed additions to Articles 56 and 57 in the working group's discussion paper of May 22, 2026, provided that this remains an option left to the discretion of Member States.

S'agissant de la proposition de compromis de la présidence sur le règlement 1831/2003 relatif aux additifs destinés à l'alimentation des animaux

Quatrième compromis de la Présidence (Fourth Presidency compromise)	Propositions rédactionnelles, en bleu (Drafting suggestions, in blue)	Commentaires (Comments)
[39) Regulation (EC) No 1831/20036 sets out the grounds and procedures for authorisation of feed additives in the Union. **To simplify the existing legal framework, Regulation (EC) No 1831/2003 should not apply to feed additives, premixtures and other feed containing them intended for export to third countries. However, such a derogation should be applicable only subject to specific requirements concerning the feed additives, as well as the labelling and the packaging of the feed additives, the premixture or the other feed containign them, to facilitate the correct application and enforcement of the Regulation.**	(39) Regulation (EC) No 1831/2003[6] sets out the grounds and procedures for authorisation of feed additives in the Union. **In order to simplify the existing legal framework, it should be clarified that Regulation (EC) No 1831/2003 ~~should~~ does not apply to feed additives~~,~~ ~~premixtures~~ and ~~other~~ feed containing them which are intended for export to third countries. However, such a derogation should be applicable only subject to specific requirements ~~conditions~~ concerning those products ~~the feed additives, as well as~~ including in particular certain ~~the~~ labelling and packaging requirements ~~of the feed additives, the premixture or the other feed containign them~~, to ensure traceability and to facilitate the correct application and enforcement of the Regulation**. **In addition, such derogation is without prejudice to the application of relevant Union law to the products concerned, such as other Union law on animal feed and the provisions of Regulation (EC) No 178/2002, as appropriate.**	Les autorités françaises sont favorables aux modifications introduites par le compromis, notamment à l'inclusion de la référence aux aliments pour animaux contenant des additifs. Les propositions rédactionnelles correspondent à celles transmises par la Commission pendant le groupe du 22 mai. Les autorités françaises y sont favorables. Effectivement, il n'est pas nécessaire de mentionner les prémélanges car ceux-ci sont déjà couverts par « feed containing them ». Les autorités françaises soutiennent également l'ajout d'un rappel que ces dispositions sont sans préjudice des principes généraux de la législation en matière d'alimentation animale, notamment en ce qui concerne la traçabilité et l'exportation d'aliments pour animaux (article 12 du R178/2002 et article 25 du R183/2005). *Traduction de courtoisie / Courtesy translation :* *The French authorities are in favour of the changes brought by the compromise, in particular the inclusion of a reference to feed containing feed additives.* *The re-drafting suggestions are those sent by the Commission during the group of May 22th. The French authorities support them.*

		Indeed, it is not necessary to target premixtures as they are already covered by « feed containing them ». *The French authorities also support the addition of a reminder that these provisions are without prejudice to the general principles of feed law, in particular regarding traceability and export of feed (Article 12 of R178/2002 and Article 25 of R183/2005).*
(44) The implementation of the procedures for modification of authorisation of feed additives, as laid down in Regulation (EC) No 1831/2003, are in some cases too burdensome or could be improved in terms of clarity and coherence. In particular, requests for modification of the holder of an authorisation should be handled as an administrative change and addressed in the ~~Community~~ **Union** Register of Feed Additives, rather than be included in the terms of the Regulation granting the authorisation. **To avoid unnecessary administrative burden, feed additives produced and labelled before such a change in the Register should be allowed to be placed on the market afterwards without relabelling.** In order to ensure uniform conditions for the implementation of Regulation (EC) No 1831/2003, implementing powers should be conferred on the Commission to amend Regulations granting an authorisation adopted before the entry into force of this Regulation, and which include the name of the holder of the authorisation, to remove such name from those	(44) The implementation of the procedures for modification of authorisation of feed additives, as laid down in Regulation (EC) No 1831/2003, are in some cases too burdensome or could be improved in terms of clarity and coherence. In particular, requests for modification of the holder of an authorisation should be handled as an administrative change and addressed in the ~~Community~~ **Union** Register of Feed Additives, rather than be included in the terms of the Regulation granting the authorisation. **To avoid unnecessary administrative burden and since safety reasons do not require the immediate adaptation of all existing stocks of the products concerned, feed additives produced and labelled before such a change in the Register should be allowed to be placed on the market afterwards ~~without relabelling~~.** In order to ensure uniform conditions for the implementation of Regulation (EC) No 1831/2003, implementing powers should be conferred on the Commission to amend Regulations granting an	Les autorités françaises peuvent soutenir la modification rédactionnelle proposée par la Commission le 22 mai. Par ailleurs, elles proposent de **supprimer la référence au réétiquetage (« without relabelling »).** Les mesures transitoires en cas de changement de titulaire sont nécessaires pour permettre l'écoulement des stocks d'additifs dont le premier metteur sur le marché est l'ancien titulaire. En revanche, le changement de titulaire n'a pas de conséquence directe en matière d'étiquetage, car l'identité du titulaire ne fait pas partie des mentions d'étiquetage obligatoires. *Traduction de courtoisie / Courtesy translation :* *The French authority can support the redrafting suggestion presented by the Commission on May 22th.* *Furthermore, they propose to **delete the reference to relabelling (« without relabelling »).** Transitional measures when the holder changes are needed to allow for the exhaustion of stocks of the additive for which the first placer on the market is the former holder.*

Regulations and include it in the ~~Community~~ **Union** Register of Feed Additives instead. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council**8**.	authorisation adopted before the entry into force of this Regulation, and which include the name of the holder of the authorisation, to remove such name from those Regulations and include it in the ~~Community~~ **Union** Register of Feed Additives instead. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[8].	*However, the change of holder has no direct effect on the labelling, since the identity of the holder is not a mandatory labelling particular.*
(48) Regulation (EC) No 1831/2003 lays down the labelling requirements applicable to feed additives and premixtures and requires displaying extensive information on a label in a physical form attached to the packaging or the container. In order to take into account the broader **concept of** labelling means ~~allowed~~ **as defined** in Regulation (EC) No 767/2009 of the European Parliament and of the Council**9** for feed materials and compound feed, the development of new, digital, communication means, and to allow more flexibility in the labelling practices and to reduce burden associated with the printing and update of physical labels by the operators, labelling by digital means should be permitted for certain non-safety related information under certain conditions of accessibility and reliability. For the purpose of ensuring the safe use of feed additives, all safety-critical and essential use information, which is in particular included in the authorisation, should however remain mandatory	(48) Regulation (EC) No 1831/2003 lays down the labelling requirements applicable to feed additives and premixtures and requires displaying extensive information on a label in a physical form attached to the packaging or the container. In order to take into account the broader **concept of** labelling means ~~allowed~~ **as defined** in Regulation (EC) No 767/2009 of the European Parliament and of the Council[9] for feed materials and compound feed, the development of new, digital, communication means, and to allow more flexibility in the labelling practices and to reduce burden associated with the printing and update of physical labels by the operators, labelling by digital means should be permitted for certain non-safety related information under certain conditions of accessibility and reliability. For the purpose of ensuring the safe use of feed additives, all safety-critical and essential use information, which is in	Les autorités françaises peuvent accepter la modification rédactionnelle proposée par la Commission le 22 mai. *Traduction de courtoisie / Courtesy translation :* *The French authority can support the redrafting suggestion presented by the Commission on May 22th.*

on the physical label. Accordingly, a distinction should be made in the context of the requirements for feed additives and premixtures between the concepts of 'labelling' and of 'label', which should be properly defined in line with the corresponding definitions laid down in Regulation (EC) No 767/2009 in order to ensure consistency. In addition, clarification should be brought concerning the labelling responsibility, in line with the provisions of Regulation (EC) No 767/2009 regarding feed labelling. Article 2 and Article 16 of Regulation (EC) No 1831/2003 should therefore be amended accordingly.	particular included in the authorisation, should however remain mandatory on the physical label. Accordingly, a distinction should be made in the context of the requirements for feed additives and premixtures between the concepts of 'labelling' and of 'label', which should be properly defined ~~in line with~~ **by a reference to** the corresponding definitions laid down in Regulation (EC) No 767/2009 in order to ensure consistency. In addition, clarification should be brought concerning the labelling responsibility, in line with the provisions of Regulation (EC) No 767/2009 regarding feed labelling. Article 2 and Article 16 of Regulation (EC) No 1831/2003 should therefore be amended accordingly.	
(49) In order to keep Regulation (EC) No 1831/2003 in line with technical progress and the digitalisation of the society, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of supplementing **or amending** ~~the~~**that** Regulation by establishing rules to enhance and facilitate labelling of feed additives and premixtures by the use of digital means. Those rules may relate to the nature of the information concerned, excluding safety-critical and essential-use information, and to the type of digital means that may be	(49) In order to keep Regulation (EC) No 1831/2003 in line with technical progress and the digitalisation of the society, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of supplementing **or amending** ~~the~~**that** Regulation by establishing rules to enhance and facilitate labelling of feed additives and premixtures by the use of digital means. Those rules may relate to the nature of the information concerned, excluding safety-critical and essential-use information,	Les autorités françaises peuvent accepter la modification rédactionnelle proposée par la Commission le 22 mai. *Traduction de courtoisie / Courtesy translation :* *The French authority can support the redrafting suggestion presented by the Commission on May 22th.*

used. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making10. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. Article 21a of Regulation (EC) No 1831/2003 should therefore be amended accordingly.	and to the type of digital means that may be used. **In addition, in order to facilitate controls while ensuring the effective functioning of the internal market and to take into account technical progress, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the establishment of acceptable tolerances for the labelled compositional values of additives or premixtures.** It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[10]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. Article 21a of Regulation (EC) No 1831/2003 should therefore be amended accordingly.	
N/A	**(49a) In order to ensure consistency with more recent Union law**	Les autorités françaises peuvent soutenir ce nouveau considérant proposé par la Commission le 22 mai.

	concerning placing on the market and use of feed, certain definitions laid down in Regulation (EC) No 1831/2003 should be replaced by a reference to definitions provided for in Regulation (EC) No 767/2009.	*Traduction de courtoisie / Courtesy translation :* *The French authority can support this new recital proposed by the Commission on May 22th.*
Article 6		
(-1b) In Article 1, paragraph 2, the following point (c) is added: **'(c) feed additives, ~~and~~ premixtures and other feed containing them,** which are intended for export to third countries, provided that they comply with the following conditions: (i) the feed additives shall not consist of antibiotics, other than coccidiostats or histomonostats; (ii) the feed additives, ~~and~~ premixtures **and other feed containing them** shall be kept in closed packages or closed containers which shall be closed in such a way that the fastener is damaged on opening and cannot be re-used; (iii) the packaging or container shall bear a **label indicating in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member States in which the feed additives, ~~and~~ premixtures and other feed containing them are ~~transferred~~ located until export:** - **the mention "only for EXPORT – not**	**(-1b) In Article 1, paragraph 2, the following point (c) is added:** **'(c) feed additives~~, and premixtures~~ and ~~other~~ feed containing them,** which are intended for export to third countries, provided that they comply with the following conditions: (iv) the feed additives shall not consist of antibiotics, other than coccidiostats or histomonostats; (v) the feed additives~~, and premixtures~~ **and ~~other~~ feed containing them** shall be kept in closed packages or closed containers which shall be closed in such a way that the fastener is damaged on opening and cannot be re-used; (vi) the packaging or container shall bear a **label indicating in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member States in which the feed additives~~, and premixtures~~ and ~~other~~ feed containing them are ~~transferred~~ located until export:** - **the mention "only for EXPORT – not ~~to be used as or in~~**	Les autorités françaises remercient la Commission pour deux améliorations majeures : - l'inclusion de « feed containing them » dans le champ de cette disposition. En effet, le régime dérogatoire doit pouvoir concerner tout aliment pour animaux destiné à l'exportation, contenant un additif non autorisé en UE ou ne respectant pas les conditions d'utilisation de son autorisation ; - le remplacement de « transferred », terme juridiquement ambigu, par « located ». Ceci permet d'éviter des controverses quant à la notion de mise sur le marché. Les autorités françaises rappellent que l'objectif de cette disposition est de redonner un cadre légal à la circulation (i.e. mise sur le marché) préalable à l'exportation, d'additifs non autorisés ou d'aliments en contenant. En cohérence avec le considérant (39), les autorités françaises proposent de supprimer la référence aux prémélanges, ceux-ci étant compris dans « feed containing them ». *Traduction de courtoisie / Courtesy translation :* *The French authorities thank the Commission for two major improvements :* *- the inclusion of « feed containing them » in the scope of this provision. Indeed, this exemption must apply to any feed*

~~to be used as or in~~ for feeding animals in the EU"; **- the designation of the feed additive, including the name of the active substances contained therein;** **- the name or business name and the address or registered place of business of the establishment producing and processing the additives, ~~and~~ premixtures and other feed containing them;** **- where applicable, the approval number of the establishment producing and processing the additives, ~~and~~ premixtures and other feed containing them, pursuant to Article 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council (*) ;** **- the batch reference number and date of manufacture.**	**for feeding animals in the EU";** **- the designation of the feed additive, including the name of the active substances contained therein;** **- the name or business name and the address or registered place of business of the establishment producing and processing the additives~~, and premixtures~~ and ~~other~~ feed containing them;** **- where applicable, the approval number of the establishment producing and processing the additives~~, and premixtures~~ and ~~other~~ feed containing them, pursuant to Article 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council (*) ;** **- the batch reference number and date of manufacture.**	*intended for export, which contains a feed additive not authorised in the EU, or not complying with the conditions of use set in its authorisation ;* *- the replacement of « transferred », a legally ambiguous term, by « located ». This allows to avoid controversies regarding the notion of placing on the market. The French authorities recall that the goal of this provision is to re-establish a legal basis for the circulation (i.e. placing on the market), prior to export, of unauthorised feed additives, or feed containing them.* *In consistency with recital (39), the French authorities propose to delete the mention of premixtures, since they are already covered by « feed containing them ».*
(2) Article 3, paragraph 3, is replaced by the following: […]	(2) **Article 3 is amended as follows :** **(a) in paragraph 1, after the words "a feed additive", the words "or any feed containing it" are added;** **(b)** paragraph 3~~,~~ is replaced by the following: […]	Les autorités françaises ont déjà proposé d'ajouter la précision "or any feed in which such a feed additive is present", pour clarifier que les règles de mise sur le marché et d'utilisation des additifs s'appliquent aussi aux aliments les contenant (prémélanges, aliments composés …). Cette précision existe déjà pour les additifs alimentaires, dans des

		termes similaires (règlement (CE) n°1333/2008, article 5). La Commission avait répondu que cela n'était pas nécessaire car l'incorporation d'un additif dans un aliment est déjà couverte par la disposition actuelle (« process » et « use »). Les autorités françaises tiennent néanmoins à souligner que cet argument ne couvre que l'incorporation réalisée dans l'UE. Cela s'applique donc aux aliments fabriqués dans l'UE, mais pas aux aliments importés contenant des additifs. Il est donc nécessaire que la disposition couvre aussi, plus explicitement, les aliments contenant des additifs. De plus, la notion de « and feed containing them » ayant été, à juste titre, introduite à l'article 1, il est également approprié, par cohérence, qu'elle soit visée aussi ici. *Traduction de courtoisie / Courtesy translation :* *The French authorities have already proposed to introduce the precision "or any feed in which such a feed additive is present", to further clarify that the rules for placing on the market and using feed additives also apply to feedingstuffs containing them (premixtures, compound feed …). The same precision is already present for food additives, in similar wording (Regulation (EC) No 1333/2008, Article 5).* *The Commission answered that it was not necessary, since the incorporation of a feed additive in a feed was already covered in the current provision (« process » and « use »).* *The French authorities, however, must underline that this argument only applies to incorporation done in the EU. Thus, this applies to feed manufactured in the EU, but not to imported feed containing*

		additives. It is necessary, therefore, that the provision cover also, more explicitly, feed containing feed additives. *Moreover, since the notion of « and feed containing them » has been, rightly, introduced in Article 1, it is also appropriate, for consistency, to include it here.*
Article 13		
1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation still meets the conditions set out in this Regulation, taking into account scientific and technological developments. In order to prepare its opinion, the Authority may, where appropriate, request the person who was the applicant for the authorisation concerned, or, where applicable, the holder of the authorisation, to submit within a specified time information and data relevant to the assessment **and shall forthwith transmit such information and data received to the Member States and to the Commission**. It shall forthwith transmit its opinion to the Commission, to the Member States and, where applicable, to the holder of the authorisation. The opinion shall be made public.	1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation still meets the conditions set out in this Regulation, taking into account scientific and technological developments. In order to prepare its opinion, the Authority may, where appropriate, request the person who was the applicant for the authorisation concerned, or, where applicable, the holder of the authorisation, to submit within a specified time information and data relevant to the assessment **and shall forthwith transmit such information and data received to the Member States and to the Commission**. It shall forthwith transmit its opinion to the Commission, to the Member States and, where applicable, to the holder of the authorisation. The opinion shall be made public. **1a. (a) Without prejudice to point 1, for feed additives whose authorisation is unlimited in time, the Commission shall periodically, after consulting the Authority, adopt implementing acts in**	La proposition de la Commission supprime, pour la majorité des additifs, un réexamen périodique automatique (lors du renouvellement) de l'adéquation des autorisations en vigueur. Cependant, la pratique a montré que même si le renouvellement ne conduisait que rarement à retirer ou restreindre l'autorisation, il permettait fréquemment d'identifier des points nécessitant d'être vérifiés et/ou amendés, pour des raisons scientifiques, techniques et/ou juridiques. Exemples : - motifs scientifiques : une nouvelle ligne directrice de l'EFSA est applicable et change l'appréciation de la sécurité de l'additif (ex : pour l'environnement) ; les références pour les méthodes d'analyse ont évolué ; etc. - motifs techniques : l'additif n'est plus fabriqué/mis sur le marché ; il contient des impuretés qui ne sont pas mentionnées dans la description mais pour lesquelles, depuis son autorisation, la Commission a pris l'habitude de fixer des limites dans des autorisations similaires ; - motifs juridiques : depuis son autorisation, certaines dispositions ont été incluses dans des autorisations similaires, ou reformulées, ou abandonnées, ce qui fait que l'autorisation n'est plus cohérente. Ex : disposition sur l'usage en tant que préparation.

	accordance with the examination procedure referred to in Article 22(2), identifying feed additives or groups of feed additives for which it is appropriate to verify whether their autorisation or specific aspects thereof, taking into account scientific and technological developments, still meets the conditions set out in this Regulation. **(b) The identification of the feed additives concerned shall take into account, among others, the date of the latest assessment, new scientific or technical knowledge, indications of safety concerns for human or animal health or the environment, available monitoring data, and may take into account requests from Member States.** **(c) In particular, the Commission shall adopt an implementing act identifying all relevant feed additives when the implementing rules established in application of Article 7(4), or the guidelines established in application of Article 7(5), have been amended.**	Il est impératif que ce travail de vigilance sur les autorisations en vigueur perdure. Il en va non seulement de la sécurité des additifs, mais aussi de l'égalité de traitement entre les autorisations anciennes et les plus récentes. Notamment, si les principes d'évaluation ou les dispositions d'utilisation sont renforcés pour les nouveaux additifs, il convient de veiller à ce que les additifs déjà autorisés ne soient pas injustement avantagés par rapport aux nouveaux additifs. La Commission a indiqué que toute vigilance et réévaluation jusqu'ici faite dans le cadre du renouvellement (article 14) pourrait continuer à être faite dans le cadre de l'article 13(1). Cependant, l'article 13(1) ne prévoit pas de déclencheurs précis. Notamment, rien ne garantit qu'un travail de vigilance sera fait pour identifier, à une fréquence adéquate, les autorisations susceptibles de ne plus être à jour et de nécessiter une réévaluation et/ou un amendement. Il est donc à craindre que ce travail de vérification ne soit, en pratique, pas fait ; ou que les additifs éventuellement identifiés comme pertinents le soient ponctuellement, de manière désorganisée, sans cohérence et sans visibilité par le secteur. Si ce travail n'est pas fait, cela constituera un recul inacceptable en matière du niveau de protection prévu par le règlement, et une distorsion massive de traitement entre les additifs « historiques » et les nouveaux additifs. S'il est fait sans organisation particulière, il en résultera un manque de visibilité et d'anticipation pour les professionnels et pour l'EFSA.

		Les autorités françaises jugent donc indispensable que l'article 13 offre certains garde-fous garantissant que les additifs historiques continueront, de manière proportionnée, à faire l'objet d'une veille permettant d'identifier les besoins de réévaluation ou d'amendement. Elles proposent que ces garanties prennent la forme d'un programme de travail que la Commission définirait périodiquement, par voie d'actes d'exécution, avec la contribution de l'EFSA et les Etats membres. Les autorités françaises tiennent à souligner : - que la proposition de la Commission prévoit des garanties de ce type (mutatis mutandis) dans le cluster B, dans une situation similaire de renoncement aux réévaluations systématiques ; - que **l'inclusion de ce mécanisme n'empêchera pas la proposition de constituer une simplification très importante par rapport à l'existant.** En effet, la fréquence et l'ampleur du réexamen pourront être adaptées au cas par cas et non plus soumises à une fréquence de 10 ans. De plus, les professionnels n'auront plus à déposer des dossiers de renouvellement, mais uniquement à répondre aux demandes éventuelles de l'EFSA. *Traduction de courtoisie / Courtesy translation :* *The Commission's proposal deletes, for the majority of feed additives, the periodic automatic re-assessment (upon renewal) of the adequacy of existing authorisations.* *However, practice has shown that even though renewal rarely led to the withdrawal or restriction of the authorisation, it frequently allowed to identify some points for which a check and/or an amendment was needed, for*

		scientific, technical and/or legal reasons. *For example :* *- scientific reasons : a new EFSA guidance has become applicable and changes the assessment of the additive's safety (e.g. for the environment) ; the references for analytical methods have change ; etc.* *- technical reasons : the additive is no longer manufactured/placed on the market ; it contains impurities not addressed in its description but for which, since its authorisation, the Commission has started setting limits in similar authorisations ;* *- legal reasons : since its authorisation, some provisions have been included in similar authorisations, or reworded, or deleted, which means the authorisation has become inconsistent. E.g. the provision about the use as a preparation.* *It is imperative that this vigilance/reviewing about existing authorisations is maintained. It is necessary for the safety of feed additives, but also for the equal treatment of « old » VS « new » feed additives.* *Notably, if the principles of assessment or the provisions of use are reinforced for new additives, it must be checked that additives already authorised are not put at an unfair advantage compared to new additives.* *The Commission has stated that any such vigilance and re-assessment done, up to now, during the renewal (Article 14) could and would still be done on the basis of Article 13(1).* *However, Article 13(1) does not include any precise triggers. Notably, nothing ensures that a work of vigilance/ « reviewing » will be done to identify, at an adequate frequency, existing authorisations that are*

		susceptible of no longer being up to date and of needing re-assessment and/or amendment. *Thus we fear that this « checking » work will, in practice, not be done ; or that, if some additives are identified as relevant, it will be done sporadically and in a disorganized manner, without any consistency nor visibility for the sector.* *It this work is not done, it will be an unacceptable step backwards regarding the level of protection provided by the Regulation, as well as a massive inequality of treatment between « historic » additives and new additives.* *If the work is done but without any particular structure, i twill result in a lack of visibility and anticipation for the operators and for EFSA.* *The French authorities therefore think it is essential that Article 13 offers some safeguards guaranteeing that historic additives will still, in a proportionate manner, be subject to some reviewing in order to identify the needs for re-assessment or amendment.* *They propose that such guarantees take the form of a work programme that the Commission would periodically establish, by ways of implementing acts, with input from EFSA and Member States.* *The French authorities want to emphasize :* *- that the proposal from the Commission provides similar guarantees (mutatis mutandis) in cluster B, for a similar situation where systematic re-assessments are abandoned ;* *- **that the inclusion of such a mechanism would not prevent the proposal to achieve significant simplification compared to the current** **state**. Indeed, the frequency and scope*

		of reviewing could be adapted on a case-by-case basis instead of being subject to a 10-year frequency. Moreover, operators will no longer have to submit renewal dossiers, but only to answer eventual requests from EFSA.
Article 14		
	5. Where an application is submitted in accordance with Article 14 (1), but is subsequently withdrawn, information of such withdrawal shall be made available to the public in the Register. The feed additives concerned and feed containing them, produced and labelled before that date, may continue to be placed on the market and used until stocks are exhausted. **6. By derogation to paragraph 5, if safety concerns are identified, a Regulation shall be adopted, in accordance with the procedure referred to in Article 22(2), requiring the additives concerned and feed containing them to be withdrawn from the market.**	Les autorités françaises ont déjà signalé cette problématique de l'article 14. Dans le système actuel, lorsqu'une demande de renouvellement est déposée (prolongeant l'autorisation au-delà de sa date d'expiration) mais est retirée par la suite, l'autorisation cesse d'être en vigueur dès notification de ce retrait. Aucune mesure transitoire n'est prévue concernant les stocks d'additifs et d'aliments en contenant sur le marché. Cette problématique a déjà été rencontrée pour des coccidiostatiques, et continuera donc d'être un enjeu même si le principe du renouvellement devait être limité à ces seuls additifs. La Commission avait reconnu l'existence de ce problème, mais s'était déclaré défavorable à l'adoption de règlements d'exécution au cas par cas, qui n'iraient pas dans le sens de la simplification. Elle avait cependant indiqué que des options alternatives pourraient être examinées. Les autorités françaises proposent donc un système prévoyant automatiquement une période transitoire pour l'écoulement des stocks existants ; seuls les cas où des motifs de sécurité sont identifiés nécessiteraient de prendre un règlement de retrait du marché. *Traduction de courtoisie / Courtesy translation :*

		The French authorities already signaled this issue with Article 14. Under the current system, when a renewal application is submitted (extending the authorization beyond its expiry date) but is subsequently withdrawn, the authorization ceases to be valid upon notification of this withdrawal. No transitional measures are planned concerning the stocks of additives and feeds containing them that remain on the market. *This issue has already arisen with coccidiostats, and will therefore continue to be relevant even if the renewal mechanism should be in the future limited to only these additives.* *The Commission acknowledged the issue, but was unfavourable to the adoption of individual implementing regulations, since that would not go in the direction of simplification. However the Commission indicated hat alternative options could be considered.* *Thus the French authorities propose a system providing an automatic transitional period for the exhaustion of existing stocks ; only cases where safety reasons have been identified would need to adopt an implementing act for the withdrawal of the market.*
Article 16		
1. The person responsible for the labelling shall be the feed business operator established within the Union who first places the feed additive or the premixture of additives on the market or, where applicable, the feed business operator under whose name or business name the feed additive or the premixture ~~of~~ ~~additives~~ is placed on the market.	**1.** The person responsible for the labelling shall be the feed business operator established within the Union who first places the feed additive or the premixture of additives on the market or, where applicable, the feed business operator under whose name or business name the feed additive or the premixture ~~of~~ ~~additives~~ is placed on the market.	1) **Les autorités françaises ne sont pas favorables à la modification proposée à l'article 16(2)(a)** (au lieu du groupe fonctionnel, indiquer la catégorie pour les additifs visés à l'article 6(1)(e), c'est-à-dire les coccidiostatiques et histomonostatiques). Cette disposition conduirait à indiquer « coccidiostatiques et histomonostatiques » pour identifier des additifs qui sont des coccidiostatiques ; cela alourdirait

2. A feed additive or premixture ~~of additives~~ shall not be placed on the market unless a label is attached to its packaging or container and bears the following information, in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member State in which it is marketed, in relation to each additive contained in the material: (a) the specific name given to the additives upon authorisation, preceded by the name of the functional group **or, in case of feed additives referred to in Article 6(1), point (e), the category** referred to in the authorisation; (b) the name or business name ~~and the address or registered place of business~~ of the person responsible for the labelling referred to in this Article, and, where the producer is not the person responsible for the labelling, the name or business name and address of the producer; **(ba) the address or registered place of business of the person responsible for the labelling referred to in this Article, and, where the producer is not the person responsible for the labelling, the address of the producer;** (c) the net weight or, in the case of liquid additives and premixtures, either the net volume or the net weight; (d) where appropriate, the approval number of the establishment placing on the market, and where applicable, that of the establishment producing the additive or the premixture, pursuant to Article 10 of Regulation (EC) No 183/2005 of the European	**2.** A feed additive or premixture ~~of additives~~ shall not be placed on the market unless a label is attached to its packaging or container and bears the following information, in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member State in which it is marketed, in relation to each additive contained in the material: (a) the specific name given to the additives upon authorisation, preceded by the name of the functional group ~~or, in case of feed additives referred to in Article 6(1), point (e), the category~~ referred to in the authorisation; (b) the name or business name ~~and the address or registered place of business~~ of the person responsible for the labelling referred to in this Article, and, where the producer is not the person responsible for the labelling, the name or business name and address of the producer; **(ba) the address or registered place of business of the person responsible for the labelling referred to in this Article, and, where the producer is not the person responsible for the labelling, the address of the producer;** (c) the net weight or, in the case of liquid additives and premixtures, either the net volume or the net weight; (d) where appropriate, the approval number of the establishment placing on the market, and where applicable, that of the establishment producing the additive or the premixture, pursuant to Article 10 of Regulation (EC) No 183/2005 of the European	l'étiquette et rendrait l'information moins claire. Le problème est lié au fait que l'annexe I du règlement ne prévoit pas, actuellement, de groupes fonctionnels pour cette catégorie. **La solution adéquate n'est pas la modification de l'article 16(2)(a), mais une modification de l'annexe I, par voie d'actes délégués, pour créer les groupes fonctionnels adéquats (« coccidiostatiques » et « histomonostatiques »).** 2) Les autorités françaises proposent de prendre en compte, à l'article 16(3), le cas des substances aromatiques avec une teneur maximale recommandée. Ce cas nécessite, actuellement, d'inclure une disposition dédiée dans chaque autorisation individuelle ; pour la simplification, il est approprié de prévoir ce cas directement dans le règlement, comme cela a été fait pour les aliments composés (R2017/2279 modifiant les annexes VI et VII du R767/2009). 3) Les autorités françaises renouvellent leur proposition d'introduire une flexibilité d'étiquetage pour les additifs et prémélanges livres dans des conteneurs ; ceux-ci ne se prêtant pas à l'apposition d'une étiquette. Il s'agit d'une possibilité qui existe déjà pour les additifs alimentaires (article 22(5) du règlement (CE) n°1333/2008). La Commission avait indiqué être ouverte à cette possibilité. *Traduction de courtoisie / Courtesy translation :* *1) **The French authorities are not in favour of the proposed amendment of Article 16(2)(a)** (instead of the functional group, indicate the category for feed additives au lieu du groupe fonctionnel, indiquer la catégorie pour les additifs referred to in Article 6(1)(e), i.e. coccidiostats and histomonostats).*

Parliament and of the Council**20;**~~.~~ (e) directions for use, any safety provisions or recommendations regarding the use and handling of the additive or premixtures mentioned in the authorisation, including animal species and categories for which the additive or premixture ~~of additives~~ is intended, and other specific labelling requirements laid down in the authorisation; (f) the identification number; (g) the batch reference number**;** **(h)** ~~and~~ **the** date of manufacture. In the case of premixtures, points (b), **(ba),** (d), (e)**,** ~~and~~ (g) **and (h)** shall not apply to the incorporated feed additives. By way of derogation from the first subparagraph, the information referred to in points **(ba)**~~(b)~~, (d) and ~~(g)~~**(h)** may be provided by digital means**.** 3. For flavouring compounds, the list of additives may be replaced by the words 'mixture of flavouring compounds'. This shall not apply to flavouring compounds subject to a quantitative limitation when used in feed. 4. In addition to the information specified in paragraph 2, the label attached to the packaging or container **or, where provided for in Annex III, the written medium accompanying it,** of an additive belonging to a functional group specified in Annex III or of a premixture containing an additive belonging to a functional	Parliament and of the Council**20;**~~.~~ (e) directions for use, any safety provisions or recommendations regarding the use and handling of the additive or premixtures mentioned in the authorisation, including animal species and categories for which the additive or premixture ~~of additives~~ is intended, and other specific labelling requirements laid down in the authorisation; (f) the identification number; (g) the batch reference number**;** **(h)** ~~and~~ **the** date of manufacture. In the case of premixtures, points (b), **(ba),** (d), (e)**,** ~~and~~ (g) **and (h)** shall not apply to the incorporated feed additives. By way of derogation from the first subparagraph, the information referred to in points **(ba)**~~(b)~~, (d) and ~~(g)~~**(h)** may be provided by digital means**.** 3. For flavouring compounds, the list of additives may be replaced by the words 'mixture of flavouring compounds'. This shall not apply : **(a)** to flavouring compounds subject to a ~~**quantitative limitation**~~ **maximum content** when used in feed **;** **(b) to flavouring compounds subject to a recommended maximum content when used in feed, where the use levels on the label of the premixture would result in exceeding this content**. 4. In addition to the information specified in paragraph 2, the label attached to the packaging or	*This provision would require the label to indicate « coccidiostats and histomonostats » to identify addtives that are coccidiostats ; which would make the label more burdensome, and the information less clear.* *The issue comes from the fact that Annex I of the Regulation currently does not define functional groups for this category.* ***The adequate solution is not the amendment of Article 16(2)(a), but the amendment of Annex I by way of a delegated act, in order to create the adequate functional groups (« coccidiostats » and « histomonostats »).*** *2) The French authorities propose to take into account, in Article 16(3), the case of flavouring compounds subject to a recommended maximum content. This case currently requires the inclusion of a dedicated provision in every individual authorisation ; for the sake of simplification, it is appropriate to address this case directly in the Regulation, as it has already been done for compound feed (R2017/2279 amending Annexes VI and VII of R767/2009).* *3) The French authorities suggest again the introduction of a flexibility of labelling for additives in premixtures supplied in tankers ; since those are not suitable to being attached a label. This possibility already exists for food additives (article 22(5) of Regulation (EC) No 1333/2008). The Commission had indicated openness to the idea.*

group specified in Annex III shall bear the information provided for in ~~point 1, point 2(a)(i) and 2(b)(i) of~~ that Annex, presented in a conspicuous, clearly legible and indelible manner. 5. In the case of premixtures, the word 'premixture' shall appear on the label. Carriers shall be declared, in the case of feed materials, in compliance with Article 17(1)(e) of Regulation (EC) No 767/2009 , and, where water is used as a carrier, the moisture content of the premixture shall be declared. Only one minimum storage life may be indicated in respect of each premixture as a whole. Such minimum storage life shall be determined on the basis of the minimum storage life of each of its components. 6. Additives and premixtures shall be marketed only in closed packages or closed containers which shall be closed in such a way that the fastener is damaged upon opening and cannot be re-used. 7. The information provided by digital means shall be: 7. The information provided by digital means shall be: (a) made available on a physical ~~label~~ **document** to the competent authority upon request **in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member State in which it is marketed, in relation to each additive contained in the material**; (b) easily and directly accessible, free of charge,	container **or, where provided for in Annex III, the written medium accompanying it,** of an additive belonging to a functional group specified in Annex III or of a premixture containing an additive belonging to a functional group specified in Annex III shall bear the information provided for in ~~point 1, point 2(a)(i) and 2(b)(i) of~~ that Annex, presented in a conspicuous, clearly legible and indelible manner. 5. In the case of premixtures, the word 'premixture' shall appear on the label. Carriers shall be declared, in the case of feed materials, in compliance with Article 17(1)(e) of Regulation (EC) No 767/2009 , and, where water is used as a carrier, the moisture content of the premixture shall be declared. Only one minimum storage life may be indicated in respect of each premixture as a whole. Such minimum storage life shall be determined on the basis of the minimum storage life of each of its components. 6. Additives and premixtures shall be marketed only in closed packages or closed containers which shall be closed in such a way that the fastener is damaged upon opening and cannot be re-used. **6a. By way of derogation from paragraphs 2, 4 and 5, where additives or premixtures are supplied in tankers, all of the information may appear merely on an accompanying document relating to the**	

through all major operating systems and browsers, without a need to register in advance, to download or install applications or to provide a password, and accessible to all potential users in the Union and competent authorities for control; (c) made available for a period of two years from the date that the additive or premixture was placed on the market, including in the event of the insolvency, liquidation or cessation of activity in the Union of the economic operator that created it. 8. The Commission is empowered to adopt delegated acts in accordance with Article 21a amending Annex III to take technological progress and scientific development into account. **8a. The Commission is empowered to adopt delegated acts in accordance with Article 21a in order to supplement this Regulation by establishing permitted tolerances for discrepancies between the labelled compositional values of feed additives or premixtures and the values analysed in official controls in compliance with Regulation (EU) 2017/625 of the European Parliament and of the Council.** 9. The Commission is empowered to adopt delegated acts in accordance with Article 21a in order to supplement this Regulation by establishing rules to enhance and facilitate labelling by the use of digital	**consignment, which is to be supplied with the delivery.** 7. The information provided by digital means shall be: 7. The information provided by digital means shall be: (a) made available on a physical ~~label~~ **document** to the competent authority upon request **in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member State in which it is marketed, in relation to each additive contained in the material**; (b) easily and directly accessible, free of charge, through all major operating systems and browsers, without a need to register in advance, to download or install applications or to provide a password, and accessible to all potential users in the Union and competent authorities for control; (c) made available for a period of two years from the date that the additive or premixture was placed on the market, including in the event of the insolvency, liquidation or cessation of activity in the Union of the economic operator that created it. 8. The Commission is empowered to adopt delegated acts in accordance with Article 21a amending Annex III to take technological progress and scientific development into account. **8a. The Commission is empowered to adopt delegated acts in accordance**	

means. Those rules may relate in particular to ~~the nature of the information concerned, which may include information referred to in paragraphs 2, 4 and 5, or~~ the type of digital means that may be used. ~~Safety-critical and essential-use information, such as that included in the authorisation, shall remain on the label attached to the packaging or container referred to in paragraph 2.~~ **9a. The Commission is empowered to adopt delegated acts in accordance with Article 21a in order to amend this Regulation by establishing the information which may be provided in a digital format, which may include information referred to in paragraphs 2, 4 and 5 and in Annex III. Safety-critical and essential-use information, such as that included in the authorisation, shall remain on the label attached to the packaging or container referred to in paragraph 2.**';	**with Article 21a in order to supplement this Regulation by establishing permitted tolerances for discrepancies between the labelled compositional values of feed additives or premixtures and the values analysed in official controls in compliance with Regulation (EU) 2017/625 of the European Parliament and of the Council.** 9. The Commission is empowered to adopt delegated acts in accordance with Article 21a in order to supplement this Regulation by establishing rules to enhance and facilitate labelling by the use of digital means. Those rules may relate in particular to ~~the nature of the information concerned, which may include information referred to in paragraphs 2, 4 and 5, or~~ the type of digital means that may be used. ~~Safety-critical and essential-use information, such as that included in the authorisation, shall remain on the label attached to the packaging or container referred to in paragraph 2.~~ **9a. The Commission is empowered to adopt delegated acts in accordance with Article 21a in order to amend this Regulation by establishing the information which may be provided in a digital format, which may include information referred to in paragraphs 2, 4 and 5 and in Annex III. Safety-critical and essential-use information, such as that included in the authorisation, shall remain on the label attached to the**	

	packaging or container referred to in paragraph 2.';	

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<u>Objet</u> : Commentaires et propositions rédactionnelles des autorités françaises à la suite de la réunion du groupe de travail ad hoc sur la simplification du 29 mai 2026 sur l'omnibus X - Cluster B – Partie Biocides

<u>Proposition d'approbation illimitée des substances actives :</u>

Les autorités françaises accueillent favorablement et remercient la Présidence pour le retrait du principe d'approbation illimitée des substances actives. En revanche, elles ne sont pas favorables à la proposition de la Présidence d'augmenter les durées d'approbation des substances actives à 20 ans en première approbation (au lieu de 10 actuellement) puis à 30 ans pour le renouvellement (au lieu de 15 actuellement).

Elles souhaitent que des durées plus raisonnables soient envisagées, au maximum 15 ans en première approbation puis 20 ans pour le renouvellement, à la condition de développer des capacités de détection et de réaction à l'émergence de nouveaux risques, tels que :

- l'apparition de résistances, un phénomène bien documenté mais non couvert par un mécanisme de surveillance active dans le compromis actuel ;
- l'identification de propriétés dangereuses non caractérisées lors de l'approbation initiale ;
- les évolutions des usages ou des expositions, liées par exemple à de nouvelles pratiques industrielles.

Elles souhaitent que le paragraphe 1 de l'article 4, le paragraphe 3 de l'article 12 ainsi que le nouvel article 15a proposé soient modifiés en conséquence.

Proposition rédactionnelle pour l'article 4 (§1) :

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 ~~20~~ **a maximum period of 15** 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.*

Proposition rédactionnelle pour l'article 12 (§3) :

*3. The renewal of an approval of an active substance shall be granted for ~~30~~ **a maximum period of 20** 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.*

A shorter renewal period may be established where data gaps regarding toxicology and ecotoxicology have been identified during the assessment of the active substance.

Proposition rédactionnelle pour le nouvel article 15a :

*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 granted for ~~20~~ **15** 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].

Cependant, cet allongement à 15 ans pour les premières approbations et 20 ans pour les renouvellements doit s'accompagner d'un renforcement des dispositions de l'article 47.

Proposition rédactionnelle pour l'article 47 :

In Article 47(1), insert a new paragraph 4:

4. The Agency shall compile and analyse information submitted pursuant to this Article in order to identify trends, signals and emerging risks at Union level, including those relating to resistance, newly identified hazardous properties and changes in exposure patterns.

Where such information indicates that the conditions for the approval of an active substance or the authorisation of a biocidal product may no longer be fulfilled, the Agency shall inform the Commission and the competent authorities concerned and may recommend that a review of the approval or authorisation be initiated.

Les autorités françaises remercient la Présidence pour la prise en compte de leur proposition de compromis pour faciliter l'achèvement du programme d'examen, en suspendant temporairement les renouvellements en cours de substances actives certaines substances actives qui ont déjà été approuvées une première fois. Toutefois, elles souhaitent que cette suspension temporaire du renouvellement d'approbation soit assujettie à la condition que l'évaluation ayant conduit à cette approbation remplisse l'ensemble des conditions suivantes :

- Qu'elle ait pris en compte les critères relatifs à la perturbation endocrinienne ;
- Quelle n'ait pas conduit à identifier la substance comme candidate à substitution ;
- Quelle n'ait mis en évidence ni manques de données, ni risques inacceptables, ni besoin de données confirmatives.

Aussi, elles proposent de compléter les paragraphes ajoutés dans l'article 13(1) afin de tenir compte de l'ensemble de ces conditions.

Par ailleurs, afin de mieux anticiper la charge d'évaluation des autorités évaluatrices et d'éviter des reports d'échéance en cours d'instruction, les autorités françaises proposent d'allonger le délai de transmission des demandes de renouvellement avant l'échéance de fin d'approbation, par exemple à 3 ans en cohérence avec le délai prévu pour les substances actives phytopharmaceutiques.

Proposition rédactionnelle pour l'article 13(1) :

1. Applicants wishing to seek renewal of the approval of an active substance for one or more product-types shall submit an application to the Agency at least ~~550 days~~ ***three years*** *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~~* ***three years*** *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);

- active substances which present data gaps, or require confirmatory data, or give rise to unacceptable risks in relation to human or animal health or the environment, in particular as regards toxicology and metabolism, environmental fate and behaviour, and ecotoxicology.

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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AGRAP/2026/485 Paris, le 3 juin 2026

Objet : réponse à l'appel à commentaire de la présidence sur les clusters B et C de l'omnibus concernant la simplification et le renforcement des exigences en matière de sécurité des denrées alimentaires et des aliments pour animaux

Les autorités françaises souhaitent faire part des commentaires suivants sur les clusters B et C (sujets vétérinaires et alimentaires) de l'omnibus concernant la simplification et le renforcement des exigences en matière de sécurité des denrées alimentaires et des aliments pour animaux.
Des commentaires complémentaires concernant les dispositions modifiant les règlements 1107/2009, 625/2017 et 1831/2003, déjà portés par la France, sont rappelés en annexe.

1/ Commentaires sur la proposition de compromis de la présidence sur le règlement (CE) n°396/2005 :

❖ **<u>Concernant l'abaissement des LMR (article 14) :</u>**

La France, comme elle l'avait demandé avec un grand nombre d'États membres lors du Conseil Agriculture de juin 2025, a défendu lors de ces négociations un niveau d'automaticité supérieur.

Néanmoins, la proposition offre de solides garanties juridiques et opérationnelles qui assureront clarté et prévisibilité pour les autorités compétentes et les opérateurs professionnels.

<u>A titre de compromis</u>, la France est donc en mesure d'apporter son soutien au texte de compromis de la Présidence (doc st09089.en26).

La France remercie la Commission d'avoir formulé une proposition visant à traiter le sujet des limites maximales de résidus. Elle salue les efforts de la Présidence pour bâtir un texte de compromis qui articule le niveau d'ambition nécessaire avec l'ensemble des garanties requises sur le plan juridique et pratique.

Le sujet, identifié de longue date et régulièrement mis en avant par le monde agricole comme par les défenseurs de l'environnement et de la santé des consommateurs, est celui de la mise en cohérence, en matière de produits phytopharmaceutiques, entre les règles applicables aux denrées agricoles produites dans l'Union européenne et celles applicables aux denrées importées depuis des pays tiers. C'est une question de bon sens.

La proposition de la Présidence permet d'apporter une réponse équilibrée et juridiquement solide visant à remédier à l'écart entre les règles applicables aux uns et aux autres, un écart devenu impossible à expliquer et à justifier aux yeux des parties prenantes comme de nos opinions publiques et qui perdure au détriment de la protection de la santé du consommateur et de l'environnement.

La proposition de la Présidence a le triple mérite :

- d'aligner l'approche du Règlement 396/2005 relatif aux limites maximales de résidus, adopté il y a plus de 20 ans avec l'approche plus protectrice du Règlement 1107/2009 relatif à la mise sur le marché des pesticides ;
- de renforcer nos règles en matière d'importation, en introduisant une obligation de transmission au comité compétent1 d'un projet de règlement prévoyant l'abaissement des LMR pour les substances les plus dangereuses, fondé sur une étude d'impact ;
- de donner les garanties nécessaires sur le plan juridique (en assurant la conformité à nos engagements internationaux), tout en répondant aux situations pratiques de mise en œuvre de ces règles, notamment par l'ajout d'un délai pour écouler les stocks comme l'ont demandé les pays de l'OMC, ou la possibilité d'exception pour les produits indispensables et sans substituts.

2/ Commentaires sur la proposition de compromis de la présidence sur le règlement (CE) n°1107/2009 :

- **<u>Concernant les articles 30, 33, 37 et 40 (et considérants 5, 9 et 10) relatifs au biocontrôle :</u>**

<u>Les autorités françaises souhaitent faire part de leur ferme opposition aux modifications introduites par la Présidence dans sa dernière proposition de compromis</u>, qui n'ont pas été discutées, et qui réservent aux seules substances à faible risque les mesures prévues initialement pour le biocontrôle et de ce fait qui affaiblissent significativement la place et l'important donnée au biocontrôle dans ce règlement, en contradiction avec les objectifs affichés de transition vers un système plus durable.
60% des produits de biocontrôle actuellement autorisés au sein de l'UE pourraient être exclus de la définition telle que présentée dans le compromis de la Présidence, limitant fortement le périmètre de la simplification proposée.
En outre, la proposition de compromis concernant la définition des « substances de biocontrôle » prévoit d'ores et déjà un niveau de protection élevé en écartant de la catégorie des « substances de biocontrôle », les substances synthétiques structurellement « similaires » aux substances naturelles en cause et qui ne répondent pas aux critères des substances « à faible risque ».

- **<u>Concernant les articles 5, 14 et 18a : propositions complémentaires en lien avec la restriction du principe d'approbation illimitée des substances actives aux seules substances faibles risques :</u>**

<u>A titre de compromis</u>[1], les autorités françaises sont favorables à la proposition de la Présidence qui restreint le principe d'approbation illimitée des substances actives aux seules substances faibles risques.

[1] La France rappelle qu'elle est défavorable à la proposition initiale de la Commission prévoyant une approbation illimitée des substances actives de pesticides. Cette proposition n'est pas acceptable au regard des impacts pour la santé et l'environnement et fait l'objet en France de très nombreuses critiques de la part de la société civile. Par ailleurs, elle constitue un changement de paradigme avec un renversement de la charge de la preuve et de la responsabilité qui

Cependant, les autorités françaises expriment leur **réserve d'examen concernant la proposition de la présidence d'étendre respectivement à 15 et 20** ans les durées maximales des premières approbations et de leurs renouvellements. En tout état de cause, une telle proposition devrait être assortie de dispositions complémentaires visant à garantir dans le temps le haut niveau de protection de la santé et de l'environnement :

- Lorsque des données complémentaires toxicologiques ou écotoxicologiques sont demandées pour finaliser l'évaluation, les durées d'approbation devront être réduites afin d'inciter les demandeurs à fournir des dossiers complets.
- Ces nouvelles durées d'approbation doivent s'entendre comme des périodes maximales pour des substances actives dont la complétude des dossiers d'approbation est actée par l'Agence (hors substances faibles risques et substances candidates à substitution).
- Afin de garantir dans le temps la pertinence des mesures de gestion de risques établies dans la décision de mise sur le marché et leur adéquation avec l'évolution des connaissances scientifiques et des solutions techniques disponibles, il paraît nécessaire de renforcer la surveillance des effets non intentionnels des substances actives mises en œuvre dans les produits autorisés dans chaque Etat Membre à l'instar du dispositif de phytopharmacovigilance mise en place en France depuis 2015.

Proposition rédactionnelle Article 5

Article 5 - First approval

The first approval shall be for a period not exceeding 15 years, except for low-risk active substances for which the period shall be unlimited

A shorter period may be established where data gaps regarding toxicology and ecotoxicology have been identified during the assessment of the active substance.

Proposition rédactionnelle Article 14

Article 14 - Renewal of approval

1. Upon application, the approval of an active substance with a limited approval period shall be renewed where it is established that the approval criteria provided for in Article 4 are satisfied.

Article 4 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

Such renewal of the approval may include conditions and restrictions, as referred to in Article 6.

2. The renewal of approval shall be for a period not exceeding 20 years, except for low-risk active substances for which the period shall be unlimited.

The renewal of approval of active substances covered by Article 4(7) shall be for a period not exceeding 5 years.

A shorter period may be established where data gaps regarding toxicology and ecotoxicology have been identified during the assessment of the active substance.

Proposition rédactionnelle Article 18a

Article 18a - Targeted reassessment of active substances

reposerait sur les autorités publiques. Enfin, le caractère illimité des approbations réduirait paradoxalement la visibilité des opérateurs, dès lors qu'une substance autorisée serait réellement susceptible de réexamen à tout moment.

1.The Commission may initiate, a targeted reassessment of the approval of active substances at any time, to verify whether certain approval criteria or specific aspects thereof are, in light of current scientific and technical knowledge, met.

It may, after consulting the Authority, and in accordance with the procedure referred to in Article 79(3), adopt implementing acts identifying active substances or groups of active substances with limited or unlimited approval periods for targeted reassessment. The identification of the active substances concerned shall take into account **the information notified by authorization holders according to article 56, any other** 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.

Accordingly, Member States are encouraged to establish an official monitoring scheme on unintended effects of authorized plant protection products.

- **Concernant les articles 35(a) et 36(3) :**

La France souhaite renforcer l'harmonisation des AMM accordées dans l'Union européenne, en vue de réaliser des économies de moyens et de réduire les divergences entre Etats membres.

Elle regrette que les propositions d'amendements des autorités françaises visant à une **meilleure harmonisation des autorisations des PPP** n'aient pas été prises en compte et demandent que, compte tenu de l'importance de ce sujet, une réponse adéquate y soit apportée et que leurs propositions soient versées à la discussion :

- Amendement demandant à la Commission de présenter sous 2 ans un rapport sur la mise en place de l'AMM européenne et la redéfinition éventuelle des zones d'autorisation des PPP, accompagné au besoin d'une proposition législative (article 35a).
- Amendement à l'article 36 (art 36(3)) pour permettre un arbitrage de la Commission en cas de désaccord des EM sur une décision de reconnaissance mutuelle. La Commission peut, dans ce cadre, saisir l'Efsa sur les questions scientifiques et techniques.

Proposition rédactionnelle Article 35a

Article 35a

By [2 years], the Commission shall present a report to the European Parliament and the Council on Union authorisation of certain phytopharmaceutical products in order to facilitate their availability on the market throughout the Union. The report should be accompanied, if necessary, by appropriate legislative proposals. It should in particular consider the possibility to extend Union authorisation through a step-wise approach to different categories of phytopharmaceutical products with similar or comparable conditions of use in all Member States and the possibility to redefine PPP authorisation zones in particular by considering the Union as one zone as for products containing only biocontrol substances or low-risk active substances.

Proposition rédactionnelle Article 36 (3)

3. By way of derogation from paragraph 2 and subject to Community law, appropriate conditions may be imposed with respect to the requirements referred to in Article 31(3) and (4) and other risk mitigation measures deriving from specific conditions of use.

Where the concerns of a Member State relating to human or animal health or the environment cannot be controlled by the establishment of the national risk mitigation measures referred to in the first subparagraph, a Member State may refuse authorisation of the plant protection product in its territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to

consider that the product in question still poses an unacceptable risk to human or animal health or the environment.

That Member State shall immediately inform the applicant and the Commission of its decision and provide a technical or scientific justification therefore.

When a Member State disagree on the possibility to authorise a product in accordance with article 29, or under what conditions it can be authorised, it may request the Commission to provide guidance on the way to solve the issue. The Commission may ask the Authority for an opinion on scientific or technical questions. If necessary, a decision shall be taken, in accordance with the regulatory procedure referred to in Article 79(3), as to the decision to take.

Member States shall provide for the possibility of challenging a decision refusing the authorisation of such products before national courts or other instances of appeal.

3/ Commentaires s'agissant de la proposition de compromis de la présidence sur le règlement (CE) n°1831/2003 :

- **S'agissant de la mesure miroir relative aux antibiotiques facteurs de croissance utilisés comme additifs dans l'alimentation animale**

La France a pris note de la réponse apportée par la Commission le 22 mai mais elle ne peut pas se satisfaire d'une simple déclaration de la Commission étant donné la sensibilité de ce sujet relatif à une politique sanitaire majeure qu'est celle de la lutte contre l'antibiorésistance.

Dans certains pays tiers, même si les antibiotiques d'importance critique sont interdits en tant que promoteurs de croissance, des usages d'antibiotiques à doses faibles et continues, dites "sous-thérapeutiques", demeurent autorisés via l'aliment ou l'eau de boisson, sous certaines conditions. De tels usages, parfois présentés comme préventifs mais ayant toujours en pratique des effets de promotion de la croissance, brouillent la frontière entre les traitements médicamenteux et l'emploi d'antibiotiques comme additifs pour promouvoir la croissance d'animaux sains.

La France réitère sa demande tenant à ce que les précisions apportées par la Commission dans sa réponse écrite soient bien intégrées dans un considérant dédié du règlement (CE) n°1831/2003, tel que modifié par le règlement omnibus, en particulier à son article 6. Ce considérant devrait préciser que, s'agissant des animaux et produits d'origine animale importés, l'utilisation d'additifs pour l'alimentation animale consistant en des antimicrobiens doit être appréciée conformément aux règles de réciprocité prévues à l'article 118 du règlement (UE) 2019/6.

Proposition de rédaction du Considérant 26a :
(26a) With regard to imported animals or products of animal origin, the use of antimicrobials as feed additives for the purpose of promoting growth or to increase yield should be subject to the prohibition laid down in Article 118 of Regulation (EU) 2019/6, ensuring that such animals or products imported into the Union comply with the same standards as those produced within the Union.

Annexe : autres propositions rédactionnelles s'agissant de la proposition de compromis de la présidence

1/ Commentaires s'agissant de la proposition de compromis de la présidence sur le règlement (CE) n°1107/2009 :

- **Concernant l'article 20 relatif à l'allongement du délai de grâce :**

Les autorités françaises réitèrent leur demande que les substances les plus dangereuses, c'est-à-dire satisfaisant à un critère d'exclusion ou générant un ou des métabolites qui y satisfont, ne bénéficient pas de cet allongement du délai de grâce.

Proposition rédactionnelle pour l'article 20 (§2) :

2. The Regulation referred to in paragraph 1 shall provide for a maximum grace period that the Member States may set when withdrawing or amending authorisations for plant protection products as a result of that Regulation. That maximum grace period shall normally not exceed 6 months for the sale and distribution, and in addition a maximum of one year for the disposal, storage, and use of existing stocks of the plant protection products concerned.

Except for active substances that has one 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 that can produce metabolites having such properties, I~~I~~n case there are no other available reasonable **alternatives** to plant protection products containing the active substance concerned, the maximum grace period shall not exceed one year for the sale and distribution, and in addition a maximum of two years for the disposal, storage, and use of existing stocks of the plant protection products concerned. In case of immediate and serious concerns for human health or animal health or the environment that led to a withdrawal or non-renewal of the approval, the Regulation referred to in paragraph 1 shall provide that the Member States may not set a grace period.

- **Concernant l'article 28 relatif à la mise sur le marché des PPP utilisés pour le traitement de semences :**

Les autorités françaises soutiennent la proposition de la Présidence et souhaitent la compléter pour instaurer une exemption d'AMM pour les PPP utilisés pour traiter des semences destinées à l'export vers un pays tiers, sous réserve que la substance active contenue dans le PPP soit autorisée dans le pays de destination et qu'elle ne soit pas interdite dans l'Union européenne pour des raison de santé humaine ou de protection de l'environnement (ajout d'un h).

Proposition rédactionnelle pour l'article 28 (§2g) :

'(f) placing on the market and use of seeds and other plant reproductive material treated with plant protection products authorised for that use in at least one Member State.

'(g) the introduction and use of a plant protection product for the purpose of the treatment of seeds or other plant reproductive material in professional treatment facilities of that Member State, provided that such plant protection product is authorised for such use in at least one Member State and is not placed on the market or used for any other purpose in the Member State of introduction.';

(h) 'the introduction and use of a plant protection product for the purpose of the treatment of seeds or other plant reproductive material in professional treatment facilities of that Member State, provided that such plant protection product is authorised for such use in a third country with a plant protection product containing an active substance which has not been banned in the European Union for reasons related to the protection of health or the environment

- **Concernant l'article 67 relatif à l'accès aux données du registre phytopharmaceutique** :

Les autorités françaises regrettent la non prise en compte de leurs demandes de modification d'une disposition prévue à l'article 67 pour éviter une divulgation disproportionnée des données contenues dans les registres lorsqu'elles sont communiquées à des fins scientifiques et de retrait de la disposition

visant l'accès aux données à toutes les entités tierces. Elles demandent que cette proposition soit versée à la discussion.

Proposition rédactionnelle pour l'Article 67

Article 67 Record-keeping

1. Producers, suppliers, distributors, importers, and exporters of plant protection products shall keep records of the plant protection products they produce, import, export, store or place on the market for at least 5 years. Professional users of plant protection products shall, except for plant protection products containing as active substances only biocontrol substances, for at least 3 years, keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used.

They shall make the relevant information contained in these records available to the competent authority on request.

~~**Third parties such as the drinking water industry, retailers or residents may request access to this information by addressing the competent authority.**~~

The competent authority may deny access to personal information related to the use of plant protection products collected for statistical or scientific purposes.

The competent authorities shall provide access to such information in accordance with applicable national or Union law

- **Concernant l'article 49 relatif à l'étiquetage des semences traitées** :

Les autorités françaises prennent acte de l'intention de la Présidence de permettre l'adoption d'actes d'exécution pour l'article 49 et réaffirment leur attachement à une évolution future des modalités d'étiquetage, afin de renforcer la protection des utilisateurs finaux et d'autoriser, tout en l'encadrant, l'usage des étiquettes dépliantes (notamment via l'ajout du pictogramme de danger et des mentions d'avertissement parmi les mentions d'étiquetage obligatoires des semences traitées).

Proposition rédactionnelle pour l'article 49 (§6) :

6. Without prejudice to other Union legislation concerning the labelling of seeds and plant reproductive material, the label and documents accompanying the treated seeds and plant reproductive material shall include:

(a) the name of the plant protection product with which they were treated;

(b) its authorisation number;

(c) the Member State which authorised it;

(d) the name(s) of the active substance(s) in that product;

(e) where applicable, hazard pictograms and signal words corresponding to each hazard category assigned in accordance with Regulation (EC) No 1272/2008 to the plant protection product with which seeds were treated;

(f) hazard statements and precautionary statements as provided for in Regulation (EC) No 1272/2008 and the implementing act adopted under Article 65(1);

(g) where applicable, risk mitigation measures set out in the authorisation for that product.

The physical label may be presented in the form of a fold-out label. In that case, section 1.2.1.6 of Annex I to Regulation (EC) No 1272/2008 shall apply mutatis mutandis

2/ Commentaires s'agissant de la proposition de compromis de la présidence sur le règlement 625/2017 relatif aux contrôles officiels

❖ **Concernant l'article 50** :

Les autorités françaises rappellent les précisions demandées à la rédaction actuelle de l'article 50, paragraphe 3, pour une meilleure cohérence avec les dispositions elle-mêmes :

- Plutôt que la formulation « competent authorities may request a split », il est proposé « competent authorities may authorise the splitting » dans la mesure où ce n'est pas aux autorités compétentes de demander une scission mais qu'il leur revient de l'autoriser ;
- Ajouter l'adjectif « compliant » à la formule de fin de paragraphe « if the physical checks on parts of the consignment require more time than those on the remaining part, allowing for the release of that remaining part for which compliant official controls have been completed » dans la mesure où seuls des contrôles jugés conformes permettent la libération.

(2) in Article 50, paragraph 3 is replaced by the following:
'3. Consignments shall not be split until official controls have been performed and the Common Health Entry Document (CHED) referred to in Article 56 has been finalised in accordance with Article 56(5) and Article 57**.**, **However,** ~~unless requested by the competent authorities~~ in the case of consignments of **plants, plant products, and other objects** ~~goods~~ referred to in Article 47(1) **points** (c) **, (e) and (f), competent authorities may** ~~**request a split**~~**authorise the splitting** ~~for the purposes of performing~~ **if the** physical checks on ~~only~~ part**s** of ~~a~~ **the** consignment **require more time than those on the remaining part, allowing for the release of that remaining part for which compliant official controls have been completed**~~presented at a border control post.~~';

❖ **Concernant l'article 45** :

Les autorités françaises souhaiteraient connaître les attentes de la Commission européenne vis à vis du contrôle des végétaux et produits végétaux relevant de l'article 73 et des matériaux d'emballage en bois.

- La Commission européenne considère-t-elle que tous ces biens doivent être notifiés et donc contrôlés ?
- Si oui, considère-t-elle que tous ces biens doivent être soumis à contrôle documentaire systématique ?

Les autorités françaises considèrent que seuls les biens sélectionnés pour contrôles (selon fréquence) seraient à notifier, ces envois notifiés étant ensuite soumis à un contrôle complet (documentaire, identité et physique).
Les autorités françaises souhaitent donc s'assurer que la proposition de la Commission permette bien ce fonctionnement, ce qui ne lui semble pas évident au regard de la rédaction des articles 44 et 45.

3/ Commentaires s'agissant du règlement (CE) n°1831/2003 :

❖ **Concernant le considérant (44)** :

Les autorités françaises proposent de **supprimer la référence au réétiquetage (« without relabelling »).** Les mesures transitoires en cas de changement de titulaire sont nécessaires pour permettre l'écoulement des stocks d'additifs dont le premier metteur sur le marché est l'ancien titulaire. En revanche, le changement de titulaire n'a pas de conséquence directe en matière d'étiquetage, car l'identité du titulaire ne fait pas partie des mentions d'étiquetage obligatoires.

Proposition rédactionnelle pour le considérant (44) :

(44) The implementation of the procedures for modification of authorisation of feed additives, as laid down in Regulation (EC) No 1831/2003, are in some cases too burdensome or could be improved in terms of clarity and coherence. In particular, requests for modification of the holder of an authorisation should be handled as an administrative change and addressed in the ~~Community~~ **Union** Register of Feed Additives, rather than be included in the terms of the Regulation granting the authorisation. **To avoid unnecessary administrative burden and since safety reasons do not require the immediate adaptation of all existing stocks of the products concerned, feed additives produced and labelled before such a change in the Register should be allowed to be placed on the market afterwards ~~without relabelling~~.** In order to ensure uniform conditions for the implementation of Regulation (EC) No 1831/2003, implementing powers should be conferred on the Commission to amend Regulations granting an authorisation adopted before the entry into force of this Regulation, and which include the name of the holder of the authorisation, to remove such name from those Regulations and include it in the ~~Community~~ **Union** Register of Feed Additives instead. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[8].

❖ **Concernant l'article 1, paragraphe 2, point c) :**

Par cohérence avec les ajustements apportés au considérant (39), et pour les mêmes raisons, les autorités françaises proposent de remplacer « feed additives, premixtures and other feed containing them » par « feed additives and feed containing them ».

Proposition rédactionnelle pour l'article 1, paragraphe 2, point c) :

(c) feed additives~~**, and premixtures**~~ and ~~**other**~~ feed containing them, which are intended for export to third countries, provided that they comply with the following conditions:

(i) the feed additives shall not consist of antibiotics, other than coccidiostats or histomonostats;

(ii) the feed additives, and premixtures and other feed containing them shall be kept in closed packages or closed containers which shall be closed in such a way that the fastener is damaged on opening and cannot be re-used;

(iii) the packaging or container shall bear a label indicating in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member States in which the feed additives~~**, and premixtures**~~ and ~~**other**~~ feed containing them are transferred located until export:

- the mention "only for EXPORT – not to be used as or in for feeding animals in the EU";
- the designation of the feed additive, including the name of the active substances contained therein;

- the name or business name and the address or registered place of business of the establishment producing and processing the additives~~, and premixtures~~ and ~~other~~ feed containing them;
- where applicable, the approval number of the establishment producing and processing the additives, and premixtures and other feed containing them, pursuant to Article 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council (*);
- the batch reference number and date of manufacture.

❖ **Concernant l'article 3 :**

Les autorités françaises ont déjà proposé d'ajouter la précision "or any feed in which such a feed additive is present", pour clarifier que les règles de mise sur le marché et d'utilisation des additifs s'appliquent aussi aux aliments les contenant (prémélanges, aliments composés …).
Cette précision existe déjà pour les additifs alimentaires, dans des termes similaires (règlement (CE) n°1333/2008, article 5). La Commission avait répondu que cela n'était pas nécessaire car l'incorporation d'un additif dans un aliment est déjà couverte par la disposition actuelle (« process » et « use »).Les autorités françaises tiennent néanmoins à souligner que cet argument ne couvre que l'incorporation réalisée dans l'UE. Cela s'applique donc aux aliments fabriqués dans l'UE, mais pas aux aliments importés contenant des additifs. **Il est donc nécessaire que la disposition couvre aussi, plus explicitement, les aliments contenant des additifs. De plus, la notion de « and feed containing them » ayant été, à juste titre, introduite à l'article 1, il est également approprié, par cohérence, qu'elle soit visée aussi ici.**

Proposition rédactionnelle pour l'article 3 :

(2) **Article 3 is amended as follows :**

(a) in paragraph 1, after the words "a feed additive", the words "or any feed containing it" are added;

(b) paragraph 3~~,~~ is replaced by the following: […]

❖ **Concernant l'Article 13** :

La proposition de la Commission supprime, pour la majorité des additifs, un réexamen périodique automatique (lors du renouvellement) de l'adéquation des autorisations en vigueur. **Cependant, la pratique a montré que, même si le renouvellement ne conduisait que rarement à retirer ou restreindre l'autorisation, il permettait fréquemment d'identifier des points nécessitant d'être vérifiés et/ou amendés, pour des raisons scientifiques, techniques et/ou juridiques.**

Exemples :

- Motifs scientifiques : une nouvelle ligne directrice de l'EFSA est applicable et change l'appréciation de la sécurité de l'additif (ex : pour l'environnement ; risque « nano » ; etc.) ; les références pour les méthodes d'analyse ont évolué ; etc.
- Motifs techniques : l'additif n'est plus fabriqué/mis sur le marché ; il contient des impuretés qui ne sont pas mentionnées dans la description mais pour lesquelles, depuis son autorisation, la Commission a pris l'habitude de fixer des limites dans des autorisations similaires ;
- Motifs juridiques : depuis son autorisation, certaines dispositions ont été incluses dans des autorisations similaires, ou reformulées, ou abandonnées, ce qui fait que l'autorisation n'est plus cohérente. Ex : disposition sur l'usage en tant que préparation.

Il est impératif que ce travail de vigilance sur les autorisations en vigueur perdure. Il en va non seulement de la sécurité des additifs, mais aussi de l'égalité de traitement entre les autorisations anciennes et les plus récentes. Notamment, si les principes d'évaluation ou les dispositions d'utilisation sont renforcés pour les nouveaux additifs, il convient de veiller à ce que les additifs déjà autorisés ne soient pas injustement avantagés par rapport aux nouveaux additifs. La Commission a

indiqué que toute vigilance et réévaluation jusqu'ici faite dans le cadre du renouvellement (article 14) pourrait continuer à être faite dans le cadre de l'article 13(1). Cependant, l'article 13(1) ne prévoit pas de déclencheurs précis. Notamment, rien ne garantit qu'un travail de vigilance sera fait pour identifier, à une fréquence adéquate, les autorisations susceptibles de ne plus être à jour et de nécessiter une réévaluation et/ou un amendement. Il est donc à craindre que ce travail de vérification ne soit, en pratique, pas fait ; ou que les additifs éventuellement identifiés comme pertinents le soient ponctuellement, de manière désorganisée, sans cohérence et sans visibilité par le secteur. Si ce travail n'est pas fait, cela constituera un recul inacceptable en matière du niveau de protection prévu par le règlement, et une distorsion massive de traitement entre les additifs « historiques » et les nouveaux additifs. S'il est fait sans organisation particulière, il en résultera un manque de visibilité et d'anticipation pour les professionnels et pour l'EFSA. **Les autorités françaises jugent donc indispensable que l'article 13 offre certains garde-fous garantissant que les additifs historiques continueront, de manière proportionnée, à faire l'objet d'une veille permettant d'identifier les besoins de réévaluation ou d'amendement.** Elles proposent que ces garanties prennent la forme d'un programme de travail que la Commission définirait périodiquement, par voie d'actes d'exécution, avec la contribution de l'EFSA et les Etats membres.
Les autorités françaises tiennent à souligner :

- Que la proposition de la Commission prévoit des garanties de ce type (mutatis mutandis) dans le cluster B, dans une situation similaire de renoncement aux réévaluations systématiques ;
- Que **l'inclusion de ce mécanisme n'empêchera pas la proposition de constituer une simplification très importante par rapport à l'existant.** En effet, la fréquence et l'ampleur du réexamen pourront être adaptées au cas par cas et non plus soumises à une fréquence de 10 ans. De plus, les professionnels n'auront plus à déposer des dossiers de renouvellement, mais uniquement à répondre aux demandes éventuelles de l'EFSA.

Proposition rédactionnelle pour l'article 13 :

1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation still meets the conditions set out in this Regulation, taking into account scientific and technological developments. In order to prepare its opinion, the Authority may, where appropriate, request the person who was the applicant for the authorisation concerned, or, where applicable, the holder of the authorisation, to submit within a specified time information and data relevant to the assessment **and shall forthwith transmit such information and data received to the Member States and to the Commission**. It shall forthwith transmit its opinion to the Commission, to the Member States and, where applicable, to the holder of the authorisation. The opinion shall be made public.

1a. (a) Without prejudice to point 1, for feed additives whose authorisation is unlimited in time, the Commission shall periodically, after consulting the Authority, adopt implementing acts in accordance with the examination procedure referred to in Article 22(2), identifying feed additives or groups of feed additives for which it is appropriate to verify whether their authorisation or specific aspects thereof, taking into account scientific and technological developments, still meets the conditions set out in this Regulation.

(b) The identification of the feed additives concerned shall take into account, among others, the date of the latest assessment, new scientific or technical knowledge, indications of safety concerns for human or animal health or the environment, available monitoring data, and may take into account requests from Member States.

(c) In particular, the Commission shall adopt an implementing act identifying all relevant feed additives when the implementing rules established in application of Article 7(4), or the guidelines established in application of Article 7(5), have been amended.

- **Concernant l'Article 14 :**

Les autorités françaises ont déjà signalé cette problématique de l'article 14. Dans le système actuel, lorsqu'une demande de renouvellement est déposée (prolongeant l'autorisation au-delà de sa date d'expiration) mais est retirée par la suite, l'autorisation cesse d'être en vigueur dès notification de ce retrait. Aucune mesure transitoire n'est prévue concernant les stocks d'additifs et d'aliments en contenant sur le marché. Cette problématique a déjà été rencontrée pour des coccidiostatiques, et continuera donc d'être un enjeu même si le principe du renouvellement devait être limité à ces seuls additifs. La Commission avait reconnu l'existence de ce problème, mais s'était déclaré défavorable à l'adoption de règlements d'exécution au cas par cas, qui n'iraient pas dans le sens de la simplification. Elle avait cependant indiqué que des options alternatives pourraient être examinées. **Les autorités françaises proposent donc un système prévoyant automatiquement une période transitoire pour l'écoulement des stocks existants ; seuls les cas où des motifs de sécurité sont identifiés nécessiteraient de prendre un règlement de retrait du marché.**

Proposition rédactionnelle pour l'article 14 :

5. Where an application is submitted in accordance with Article 14 (1), but is subsequently withdrawn, information of such withdrawal shall be made available to the public in the Register. The feed additives concerned and feed containing them, produced and labelled before that date, may continue to be placed on the market and used until stocks are exhausted.
6. By derogation to paragraph 5, if safety concerns are identified, a Regulation shall be adopted, in accordance with the procedure referred to in Article 22(2), requiring the additives concerned and feed containing them to be withdrawn from the market.

- **Concernant l'Article 16 (2) :**

Les autorités françaises ne sont pas favorables à la modification proposée à l'article 16(2)(a) (au lieu du groupe fonctionnel, indiquer la catégorie pour les additifs visés à l'article 6(1)(e), c'est-à-dire les coccidiostatiques et histomonostatiques).
Cette disposition conduirait à indiquer « coccidiostatiques et histomonostatiques » pour identifier des additifs qui sont des coccidiostatiques ; cela alourdirait l'étiquette et rendrait l'information moins claire.
Le problème est lié au fait que l'annexe I du règlement ne prévoit pas, actuellement, de groupes fonctionnels pour cette catégorie.
La solution adéquate n'est pas la modification de l'article 16(2)(a), mais une modification de l'annexe I, par voie d'actes délégués, pour créer les groupes fonctionnels adéquats (« coccidiostatiques » et « histomonostatiques »).

Proposition rédactionnelle pour l'article 16, paragraphe 2, point a) :
2. A feed additive or premixture ~~of additives~~ shall not be placed on the market unless a label is attached to its packaging or container and bears the following information, in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member State in which it is marketed, in relation to each additive contained in the material:
(a) the specific name given to the additives upon authorisation, preceded by the name of the functional group ~~**or, in case of feed additives referred to in Article 6(1), point (e), the category**~~ referred to in the authorisation;

Par ailleurs, les autorités françaises rappellent, en annexe à cette note, d'autres propositions rédactionnelles visant à améliorer le règlement, qu'elles ont transmises dans leurs commentaires écrits du 29 mai 2026.

- **Concernant l'article 16 (3) :**

1) Les autorités françaises proposent de prendre en compte, à l'article 16(3), le cas des substances aromatiques avec une teneur maximale recommandée.
Ce cas nécessite, actuellement, d'inclure une disposition dédiée dans chaque autorisation individuelle ; pour la simplification, il est approprié de prévoir ce cas directement dans le règlement,

comme cela a été fait pour les aliments composés (R2017/2279 modifiant les annexes VI et VII du R767/2009).
2) Les autorités françaises renouvellent leur proposition d'introduire une flexibilité d'étiquetage pour les additifs et prémélanges livres dans des conteneurs ; ceux-ci ne se prêtant pas à l'apposition d'une étiquette. Il s'agit d'une possibilité qui existe déjà pour les additifs alimentaires (article 22(5) du règlement (CE) n°1333/2008).
La Commission avait indiqué être ouverte à cette possibilité.

Proposition rédactionnelle pour l'article 16 (3) :

3. For flavouring compounds, the list of additives may be replaced by the words 'mixture of flavouring compounds'. This shall not **apply :**
(a) to flavouring compounds subject to a ~~**quantitative limitation**~~ **maximum content** when used in feed **;**
(b) to flavouring compounds subject to a recommended maximum content when used in feed, where the use levels on the label of the premixture would result in exceeding this content.
[…]
6a. By way of derogation from paragraphs 2, 4 and 5, where additives or premixtures are supplied in tankers, all of the information may appear merely on an accompanying document relating to the consignment, which is to be supplied with the delivery.

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ITALY

ITALIA

As a preliminary remark, we wish to express our regret for the shift in the Presidency's approach regarding the unlimited duration of approvals for plant protection active substances.

The previous compromise text ensured an optimal balance: it allowed for the establishment of review programs not based on a merely administrative element—such as the expiry date of the approval—but on scientific considerations, including new information, new criteria and monitoring data. This approach would have enabled a **swifter reassessment of those substances for which concerns may have arisen**, thus allowing for a **more risk-based regulatory intervention** and a **more efficient allocation of resources** by the competent authorities.

Limiting unlimited duration exclusively to low-risk substances is a missed opportunity: it reduces the overall ambition of the proposal and results in a simplification whose scope is insufficient to address the structural problems of the plant protection products regulatory system.

We recall that in the first round of comments, Italy proposed 20 years for initial approval, and illimited period for renewal, based on the following considerations:

- Between Directive 91/414/EEC and Regulation 1107/2009, substances have been reviewed three times.

- In any case, Articles 21, 56, and 69 of the Regulation provide ample scope for reviewing substance approvals in the event of new information/data (situations requiring immediate review).

- It provides the possibility of establishing review programs based not on administrative data (approval expiration date) but on scientific evidence (new information, new criteria, monitoring, etc.), thus better rationalizing Member States' resources and enabling a more rapid review of substances that raise concerns.

Italy devotes a high priority to obtaining a 20-year period for initial approval, and illimited period for renewal.

Against this background, and while maintaining a constructive spirit to facilitate the pursuit of a balanced compromise, Italy proposes the following as a *de minimis* solution which is the same as proposed by the Commission for the BPR, which regulates biocides which in many cases are the same substances which are used also in PPPs:

- **First approval: 20 years**
- **Renewal: 30 years.**

Amendments to the latest Presidency compromise text (st9571/26)

Article 5 "First approval"

*The first approval shall be for a period not exceeding ~~15~~ **20** years, except for low-risk active substances for which the period shall be unlimited.*

Article 14 "Renewal of approval"

1. Upon application, the approval of an active substance with a limited approval period shall be renewed where it is established that the approval criteria provided for in Article 4 are satisfied.

Article 4 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

Such renewal of the approval may include conditions and restrictions, as referred to in Article 6. 2.

*The renewal of approval shall be for a period not exceeding ~~20~~ **25** years, except for active substances renewed as low-risk active substances for which the period shall be unlimited.*

Cluster C – Regulation 2017/625 Official Controls (OCR)

We can accept moving the amendment proposed by Italy under article 56 and 57 of OCR to Article 45, provided that it is included in its entirety. In fact, the latest Presidency compromise seems to be missing the part related to art. 57.

Member States wishing to require the mandatory notification of goods under Article 73 of Regulation 2016/2031 need to be able to apply, mutatis mutandis, the provisions of Article 57(2) and (3) of the OCR, in order to prevent the placing on the market of goods that have not been properly notified and subjected to the required phytosanitary controls. Therefore, customs authority inspections are imperative and indispensable to ensure the smooth functioning of the operational flow and to fulfill the objectives underlying the proposed amendment under discussion.

Amendments to the latest Presidency compromise text (st9692/26)

"(1a) in Article 45, the following paragraph is inserted:

'5. For wood packaging material as referred to in Article 43(1) of Regulation (EU) No 2016/2031 and for each consignment of plants as referred to in the lists established pursuant to Article 73 of Regulation (EU) No 2016/2031, the competent authorities may request operators responsible for the consignment to complete the relevant part of the Common Health Entry Document (CHED), providing the information necessary for the immediate and complete identification of the consignment and its destination. In such a case, Article 50(1) to (3) ~~*and*~~*, Article 56(3) to (5)* ***and Article 57 (2) and (3)*** *apply mutatis mutandis and Article 4(3) of Delegated Regulation (EU) 2024/2104 shall not apply.';*

The first subparagraph shall not apply to controls in a different Member State for consignments whose border control post of first arrival into the Union is in a Member State that does not opt for requesting a CHED.'"

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LUXEMBOURG

LUXEMBOURG

In Recital (5) point 3, add at the end “to them” to be coherent with art 3 new point 35:

(5) In order to facilitate faster market access for biocontrol substances and products containing them, biocontrol substances need to be more clearly defined and identified under Regulation (EC) No 1107/2009. A definition for biocontrol substances should include: 1) micro-organisms, 2) inorganic substances as occurring in nature, with the exception of heavy metals and their salts, 3) **substances of biological origin or produced synthetically that are functionally and structurally identical to them,** or 4) substances of biological origin or produced synthetically that are functionally identical and structurally similar to them such as…

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HUNGARY

MAGYARORSZÁG

We acknowledge the Cypriot PRES effort to try to find a balanced approach amongst the MSs various opinions related to the planned amendment of 1107/2009/EC.

However, we would like to emphasize that it is our common interest to create rules that represent the greatest possible ambition for real simplification.

In this context we would like to indicate as follows:

We cannot support the Presidency's new concept that an active substance is considered a biological active substance if it meets the criteria for low-risk active substances. On this basis, biological active substances that do not pose a higher risk but have not been authorised as low-risk active substances should not benefit from the simplification of the authorisation process. In our opinion, this amendment does not serve the original aim of the simplification proposal, which is to make as many safe biological alternatives available in plant protection as possible.

Based on the above, we cannot support the current compromised text in this regard. We consider the amendment to Article 5 of the Regulation to be a similar tightening, according to which only active substances that have been authorised as low-risk active substances may be authorised for an unlimited period. The previous compromise proposal was more ambitious and did not limit the unlimited approval to low-risk active substances only.

In the case of this tightening, we also believe that it is not in line with the Commission's original aim of simplification, so we cannot support it.

For all these reasons, we propose a return to the original Commission proposal or, alternatively, the inclusion of the Italian proposal for Article 5, which is as follows:

Article 5 – first approval

„The first apporval shall be for a period not exceeding 20 years and after for an unlimited period except for:

(a) active substances that are identified as candidates for substitution in accordance with Art. 24;

(b) active substance that are approved under Art. 4 (7);

(c) active substance for which a lmited period of approval is set in accordance with Art. 6 (j) in particular in the light of relevant uncertainties emerging from the risk assessment including as a result data gaps.”

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NETHERLANDS

NEDERLAND

1. Comments on amendments 1107/2009

We note that the current proposal should still be strengthened in order to safeguard the high level of protection for humans, animals and environment. Furthermore, we believe that it is important that the changes proposed in the omnibus Food and Feed Safety will not undermine the high level of protection of other European guidelines such as the Water Framework Directive.

We still have the following comments on the proposal:

Periodic reviews of scientific literature and monitoring data

The proposed extended approval periods for most active substances may lower the level of protection if this proposal is not joined by a safeguard that ensures timely targeted reassessment in case of new scientific or technical knowledge which is relevant for the substance. Therefore, to make sure that the level of protection is not lowered, the EC should be required to mandate EFSA to perform periodic reviews of scientific literature and monitoring data, as was included in the previous compromise text.

To do so, the text of the previous proposal for Article 18 on the periodic review (see below) should be included in Article 18a:

To include in Article 18a "*The Commission shall mandate the Authority to periodically review relevant scientific literature and, if available, monitoring data on the safety of all approved and notified active substances. The Authority shall report its findings to the Commission and the Member States.*"

This amendment is not only needed to safeguard the current level of protection, but also to simplify the procedure for product applications. By having a EU vigilance system based on these periodic reviews in place, it would be clear if the last EU-assessment of the active substance still complies with the latest state of scientific knowledge. This would not only streamline the procedure for product applications, but also ensure a higher (legal) predictability for both authorities and applicants and would ensure a level playing field across member states.

Tacit agreement limited to products containing only low risk substances

Please remove biocontrol from Article 42 (tacit agreement for mutual recognition), keeping it consistent with the amended Article 37.

Based on the proposed amendments to Article 42, the tacit agreement when not meeting the deadline would still apply to products containing biocontrol substances and is not limited to only low risk substances. We assume that this is an oversight when preparing the new compromise text, as the proposal for Article 37 for cMS product authorisations was changes to be restricted to low risk substances.

Please note that by including also biocontrol substances in Article 42 the level of protection is lowered as also products containing broad-spectrum toxic substances would be eligible for authorisation by tacit agreement while the deadline of 120 days is not realistic for this type of toxic substance.

2. MRL (EC) No 396/2005

As indicated in several Council Working Groups and the Permanent Representatives Committee on 27 May 2026, the Netherlands still has serious concerns regarding the Presidency Proposal amending Article 14 paragraph (2) of Regulation (EC) No 396/2005. The Presidency proposal (st09642/26) does not seem to reflect a balanced text taking into consideration the views of the three

different Member States groups. In the first version of the note the Presidency itself stated that „*In the latest version of its compromise text, the Presidency is proposing a mix between the Commission approach and the more stringent approach*."

From our point of view, the preferred way forward would still be to refrain from any major changes of the current procedures in Regulation (EC) No 396/2005 relating to import tolerances and Codex Maximum Residue Limits until the general Impact Assessment initiated under the Vision for Agriculture and Food has been finalized. Otherwise, it is hardly possible to reflect the actual impact of such significant amendments – i.e. even possible negative impacts to the EU.

However, we very much appreciate the efforts to enhance simplification of EU legislation, also in case of food and feed safety, and we are also willing to work towards a compromise text. Therefore, we would like to submit the following suggestions:

Amendments to proposed new subparagraph in Article 14 (2) of Regulation (EC) No 396/2005 (based on latest Presidency proposal;

NL additions in **bold,** deletions in ~~**bold**~~)

…(4) Article 14 is amended as follows:

(a) A new ~~**sub**~~paragraph **(**2a**)** is inserted:

'2a. 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 this Regulation, a MRL that has been set based on a CXL or a GAP implemented in a third country can be r**eviewed** ~~**revoked**~~ and ~~**shall be**~~ set in accordance with Article 18(1)(b) or Article 16 of this Regulation if considered appropriate based on a prior impact assessment. **The impact assessment shall take into account especially the following criteria**:

- **a risk assessment carried out by the Authority,**
- **compatibility with WTO and SPS requirements,**
- **the impact on EU Member States as well as on third countries,**
- **the needs of the entire food and feed chain.**

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

‘**2b. The provisions in Article 14 (2a) will be reviewed as soon as the general impact assessment initiated under the Vision for Agriculture and Food is available.‘**

(~~b~~**c**) A new paragraph 2~~a~~**c** is inserted:

‘2~~a~~**c**. (…)‘

Respective recitals also need to be amended accordingly (additions in **bold,** deletions in ~~**bold**~~):

‘(27) Regulation (EC) No 396/2005 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) **or at a higher limit**, ~~**if appropriate**~~ **based on a prior impact assessment. The impact assessment should follow specific criteria taking into account especially a risk assessment carried out by the Authority whether safe MRLs (CXL or GAP) could be derived, compatibility with WTO and SPS requirements, the impact on EU Member States as well as on third countries, and the needs of the entire food and feed chain.**

Since this amendment to Article 14 of Regulation (EC) No 396/2005 is considered as interim approach, the provisions should be reviewed and amended not later than six months after the results of the aforementioned impact assessment initiated under the Vision for Agriculture and Food are available.‘

3. BPR (EU 528/2012):

The Netherlands notes that the current proposal should still be strengthened on two critical points in order to safeguard the high level of protection for humans, animals and environment. We still suggest the following amendments are made to the text on the Biocidal Products Regulation:

1. A link must be established between the approval period for substances and the authorisation periods for products.

   If this is not done, the workload for national competent authorities, will increase, as work will shift from substance assessment to product authorisation. This will also lead to a reduction in harmonisation within the Union, since the granting of product authorisations is a national matter, unlike the European approval of substances. Additionally, the burden on producers, particularly SMEs, will increase, as they will no longer be able to refer to data from substance approvals and will thus have to provide separate data for each product.

Proposed amendments:

a. Replace: Article 17, paragraph (4) is replaced by the following: **(4) The authorisation shall not exceed 3 years from the earliest date of expiry of the approval of the active substances contained in the biocidal product concerned.**

b. Amend: Article 31 1. An application by or on behalf of an authorisation holder wishing to seek the renewal of a national authorisation for one or more product-types shall be submitted to the receiving competent authority at least 550 days before the expiry date of the authorisation **or at least 550 days before the date of expiry of the approval of the active substance contained in the biocidal product concerned.** Where renewal is sought for more than one product-type, the application shall be submitted at least 550 days before the earliest expiry date **or at least 550 days before the earliest date of expiry of the approval of the active substances contained in the biocidal product concerned.**

c. Amend: Article 45: 1. An application by or on behalf of an authorisation holder wishing to seek the renewal of a Union authorisation shall be submitted to the Agency at least 550 days before the expiry date of the authorisation **or at least 550 days before the earliest date of expiry of the approval of the active substances contained in the biocidal product concerned.**

2. The work programme to determine which substances should undergo early re-evaluation, as well as the mandate for the Agency to conduct a literature review on the risks of active substances, as outlined in Recital 34 in earlier previous amendment to the text must be restored, and must be included in the text of the Regulation, comparable to the Plant Protection Products Regulation.

   If the **approval period is doubled** without clear agreements on how new scientific knowledge should be identified or assessed, there is a significant risk that the **level of protection for humans, animals, and the environment will decrease.** This would also jeopardise the achievement of the Water Framework Directive objectives.

Proposed amendments:

1. **Restore previous amendments to recital 34.**
2. Add: article 15: **1. The Commission shall mandate the agency to review relevant scientific literature and, if available, monitoring data on the safety of all approved and notified active substances periodically. The Authority shall report its findings to the Commission and the Member States.**
3. Amend: article15.1: **2.** The Commission ~~may~~ **shall at least every two years, after consulting the Agency, assess the need to set a work programme to** review the approval of ~~an~~ active substance**s or groups of active substances** for one or more product-types at any time where there are significant indications that the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2) are no longer met**, or where current knowledge justifies a review**. **This work programme shall be adopted in accordance with the examination procedure referred to in Article 82(3) by way of an implementing act.**

- Without these amendments, the fundamental principle for the Netherlands that the level of protection for people, animals and the environment must not be reduced will not be met.
- Without these amendments, the aim of the simplification, to streamline procedures and reduce the burden on businesses and competent authorities, will not be achieved.

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AUSTRIA

ÖSTERREICH

- AT accepts the Presidency proposal to approve active substances for a period of **20 years** and to extend renewals to **30 years** as a reasonable compromise.

- It is also proportionate to set shorter approval periods in **individual cases** in accordance with the outcome of the risk assessment carried out prior to the approval decision.

- AT supports the possibility for the Commission to select a number of active substances for a renewal procedure based on **specific criteria**.

- We consider the new proposal to be suitable for speeding up and completing the review programme.

- We request one amendment to the draft, namely a certain **extension** of the approval period for active substances that meet the **exclusion criteria** or are **candidates for substitution**. The extension may be short - for example 3 to 5 years -, but even a short extension would provide some relief for applicants and authorities to free up resources and reduce their workload.

Following the AGS meeting on 29 May 2026, AT submits the following comments concerning Omnibus X:

ad Reg. (EC) No 396/2005 (MRL)

- According to the minutes of the AGS meeting on 29.5.2026, a proposal for the Council's negotiating mandate is expected to be submitted to COREPER II for adoption on 12.6.2026. In our opinion, this is premature, as the announced general impact assessment has not yet been published.
- As stated by Cion during the AGS meeting on 13.5.2026, the work on the **general impact assessment** is **still ongoing**. A **study** launched in November 2025 is expected to be provisionally completed by **June/July 2026.**
- This **general impact assessment** is a **key** for determining further steps. Therefore, we like to stress the necessity of the general impact assessment for the **final discussions**.
- AT supports DEs comment for a review of Article 14(2a) once the general impact assessment becomes available and considers that such a review should, where appropriate, lead to a revision of the provisions. In AT's view, the questions listed below remain regarding the interaction between Regulations (EC) 1107/2009 and 396/2005.
- Furthermore, it is considered essential that the proposed amendment with the derogation in the new subparagraph of Article 14(2) of Regulation (EC) No 396/2005 be fully incorporated into the announced general impact assessment and evaluated in detail.
- Due to the given significant implications of these decisions and the remaining unresolved discussion points particularly with regard to the proposed derogation in Article 14(2) of Regulation (EC) No 396/2005 a **scrutiny reservation** remains in place.

New subparagraphs in Article 14(2) of Regulation (EC) No 396/2005 in the second compromise proposal:

- Which active substances are affected, what is the status of their approval in third countries, what EFSA monitoring data is available for these active substances, and what is the origin of the products containing residues - including the active substances covered by the proposed exemption under Article 4(7) of Regulation (EC) No 1107/2009?
- What criteria will be established for the specific impact assessment? Will a Guidance Document be drawn up for this purpose?

- Could maximum residue levels that exceed the 'technical zero' also be set under the circumstances referred to in Article 16 of Regulation (EC) No 396/2005?
- Could authorised active substances referred to in Article 4(7) of Regulation (EC) No 1107/2009 which do not meet the criteria set out in points 3.8.3 or 3.10 of Annex II of Regulation (EC) No 1107/2009 be set at 'technical zero' under certain circumstances?

ad Reg. (EC) 1107/2009 concerning the placing of plant protection products in the market

- AT considers the amendments proposed in the third Presidency compromise text regarding the approval of active substances to be the **minimum compromise** that can still be supported. In particular, the extension of the first active substance approval from 10 to 15 years and the extension of the active substance renewal to 20 years should in any case be retained, as otherwise the intended simplification approach cannot be achieved. AT would also be open to continuing negotiations on this matter at a technical level and to developing an innovative framework for active substance approval that would address potential safety concerns.

Article 5 and Article 14:

- In light of the current discussions regarding the permanent approval of active substances, we note that there is currently no proposal capable of securing a majority in line with the Cion's proposal. We also note that, due to the lack of in-depth technical elaboration, it does not appear possible to address the criticisms levelled at the Cion's proposal within the given timeframe.
- We therefore support the current compromise text of the presidency. It is essential however, that the proposed level of ambition is at least maintained in order to remain consistent with the principle of simplification.

Article 11:

- AT opposes giving priority to certain substances, as the limited availability of resources would mean, that procedural certainty for applicants for other substances could no longer be guaranteed, and timely processing of applications would be called into question.

Article 13 (4):

- Given that the main focus of the regulation shifted towards low risk criteria, we shall ask whether the retention of this provision under paragraph 4 is intentional and the purpose of the regulatory content.

Article 18a:

- As the unlimited approval of active substances, as originally proposed by the Cion, is no longer included in the third Presidency compromise text, we no longer see any need for Article 18a and propose that it be deleted. In our view, the existing control mechanism in Article 21 is sufficient. With active substance approval remaining limited in time, an additional provision on targeted active substance reassessment does not lead to simplification.
- We request that the Presidency considers – as a minimum compromise – limiting Article 18a to active substances classified as low-risk or, in the absence of any necessity for it, deleting it.

Article 20 (2):

- The wording "in case there are no other available reasonable alternatives" in the second subsection of paragraph 2 is currently unclear. We ask the presidency if a reference to Article 4 (7) was intended or whether this is a new condition that still has to be defined.

Article 22:

- Under paragraph 2, the reference to Article 13(4) refers to biocontrols. We shall question whether the reference has to be adapted according to the focus on low-risk active Substances.

Article 23:

- Under Article 23 (1) lit b we question if a basic substance product may include a simple dilutent as well as substances necessary to stabilise the product, resulting in the wording "a simple dilutent, **and**/or substances necessary to stabilise the product.

Articles 37(5) and Article 42(3):

- AT welcomes the fact that the Member State concerned has to issue the tacit authorisation and provide the applicant with key information, such as the authorisation number. However, we would generally prefer an EU-wide harmonised approach and consider the last sentence in Art. 37(5) and 42(3) to be problematic. As some member states have reservations about the so-called „tacit agreement", we suggest a rewording and to replace the term "tacit agreement" with "simplified procedure".

"Tacit agreement" - wording proposal for Article 37(5) (also applies to Article 42(3)):
"Where the application concerns a plant protection product containing as active substances only low-risk active substances and the other Member States concerned have not adopted a decision after 120 days, the authorisation shall be deemed as having been granted by the Member States ***in a simplified procedure***. In case the authorisation is deemed to be granted, those Member States concerned shall issue the authorisation, send it to the applicant and inform of the publication of this information on the authorised plant protection product in accordance with Article 57(1), in particular the authorisation number."

Article 42 (3):

- Under Article 40, the wording "biocontrol or" was deleted. Article 42 may need to be adopted accordingly.

Article 49(2a):

- AT considers this recently introduced provision to be unclear and not particularly necessary, as the majority of cases would likely be covered by the grace period. Furthermore, this provision and the relevant background have not been explained, neither have they been discussed with the other Member States during the AGS meeting. AT would like to see this paragraph deleted from the compromise text.

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POLAND

POLSKA

Point (23) – amendments to Art. 37(5)

Drafting suggestion: Poland will not submit a drafting amendment at this stage. However, Poland does not support the provision in its current wording and strongly reiterates that adopting it would lead to different application of the rule across the EU: in some Member States an authorisation could be deemed granted after 120 days, while in others it would not.
This would create legal uncertainty and unequal treatment of applicants. It could also make controls difficult, where no formal authorisation has been issued by the competent authority.

Point (25) – amendments to Art. 42(3)

Drafting suggestion: Poland will not submit a drafting amendment at this stage. However, Poland does not support the provision in its current wording and strongly reiterates that adopting it would lead to different application of the rule across the EU: in some Member States an authorisation could be deemed granted after 120 days, while in others it would not.
This would create legal uncertainty and unequal treatment of applicants. It could also make controls difficult, where no formal authorisation has been issued by the competent authority.

In point (35) in art. 67 of the Regulation 1107/2009 new paragraph 5 should be added:
"5. Member States may exempt certain professional users from certain requirements relating to the keeping of records of the plant protection products they use, as stipulated pursuant to paragraph 4, taking into account the size of the farm, the quantity of plant protection products used or the specific nature of the production, provided that such exemption does not affect the control of the use of plant protection products."

Rationale:
Keeping electronic records of the use of plant protection products, which is mandatory under Regulation 2023/564, raises serious concerns and reservations among farmers. This obligation would be difficult to fulfil, especially for small farms and elderly farmers. At the same time, these farmers use relatively small amounts of plant protection products.
Including all data required under Regulation 2023/564 in the electronic register of plant protection treatments would also be difficult for farms cultivating many plant species, in particular ornamental plant nurseries.

Therefore Member States should have the right to derogate from this requirement. Farmers are awaiting the proposed simplification.

Article 3
Amendment to Regulation (EC) No 396/2005

Drafting suggestion:
No drafting suggestion; no additional comments

Rationale:
We accept the current compromise text proposal, maintaining our position supporting the directional proposal that MRLs should be lowered to LOQ (technical zero) if justified by an impact assessment (IA).

Article 4
Amendment to Regulation (EC) No 528/2012

Drafting suggestion:
No drafting suggestion; no additional comments

Article 5
Amendment to Regulation (EC) No 1829/2003

Drafting suggestion:
No drafting suggestion; no additional comments

Rationale:
Given the national agreements and support for the current proposed compromise text regarding GMMs, we have no additional comments. If the requirements contained in the preamble are not added to the regulations and a definition of "non-viable residual material GMM" is not included, we also accept the current wording of the regulations (in accordance with the agreements mentioned above).

Article 11
Amendments to Regulation (EU) 2017/625
Point (2) – addition of Art. 45(5)

Drafting suggestion:
"5. For wood packaging material as referred to in Article 43(1) of Regulation (EU) No 2016/2031 and for each consignment of plants as referred to in the lists established pursuant to Article 73 of Regulation (EU) No 2016/2031, the competent authorities may request operators responsible for the consignment to complete the relevant part of the Common Health Entry Document (CHED), providing the information necessary for the immediate and complete identification of the consignment and its destination. In such a case, Article 50(1) to (3), Article 56(3) to (5) **and Article 57 (2) and (3)** apply mutatis mutandis and Article 4(3) of Delegated Regulation (EU) 2024/2104 shall not apply.

The first subparagraph shall not apply to controls in a different Member State for consignments whose border control post of first arrival into the Union is in a Member State that does not opt for requesting a CHED."

Rationale:
Poland strongly supports proposed addition of Article 45(5). However for the sake of legal clarity art. 45 (5) should also refer to art. 57 (2) and (3) of the OCR.

Point (2) – amendments to Art. 50(3)
Drafting suggestion:
"3. Consignments shall not be split until official controls have been performed and the Common Health Entry Document (CHED) referred to in Article 56 has been finalized in accordance with Article 56(5) and Article 57. However, in the case of consignments of plants, plant products, and other objects referred to in Article 47(1) points (c), (e) and (f) **and/or in Article 44 (1)**, competent authorities may request a split if the physical checks on parts of the consignment require more time than those on the remaining part, allowing for the release of that remaining part for which official controls have been completed."
Rationale:

Proposed Article 50 (3) of Regulation 2017/625 indicates that the possibility of splitting consignments applies to goods indicated in Article 47(1) of that Regulation, i.e. goods regulated under Article 72 and Article 74 of the Regulation 2016/2031. However, the possibility of splitting consignments of regulated goods under Article 73 of the Regulation 2016/2031, which are controlled under Article 44 of the Regulation 2017/625, is not included.

These consignments are subject to official controls, even if such controls are performed at a frequency determined on the basis of a risk analysis. In accordance with Regulation 2019/66, identity checks and physical checks on such goods must be carried out on at least 1% of consignments (in the case of Poland, 10% of consignments are examined). Poland maintains opinion that it should also be possible to split consignments of regulated goods under Article 73. The explicit indication in the OCR provisions that consignments controlled under Article 47(1) of OCR may be split leads to the interpretation that consignments controlled under other provisions (i.e. Article 44 of OCR), or consignments combining goods controlled under Article 47(1) and Article 44 OCR, may not be split.

The amendment proposed by Poland aims to avoid legal uncertainty and ensure clarity of the provisions, as well as their uniform interpretation by Member States and business operators. The lack of indication in the draft provision of goods subject to official controls under Article 44 of the OCR may result in delays in the clearance of consignments containing both goods regulated under Articles 47(1) and 44. In such cases, as the Commission indicated during the meeting of the Standing Committee on Plant Health, the CHEDPP document is used to confirm the completion of controls. Not including goods controlled under Article 44 will make impossible the splitting of such consignments, which may result in the lower-risk part of the consignment having to be detained until the physical inspection of the regulated good under Article 47 is completed.

Article 12
Entry into force and application

Drafting suggestion:
In Article 12 the new subparagraph should be added, after the first subparagraph:
"Article 1 shall apply from [*date of entry into force of this Regulation plus 18 months*].

Rationale:
The amendments introduced to Regulation (EC) No 1107/2009 significantly changes the administrative procedures and the rules governing the actions of the competent authorities and Member States to such an extent that they will require corresponding adjustments to national legislation. In view of the above, we propose that these provisions should apply 18 months after the date of their publication in the Official Journal of the European Union.

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SLOVAKIA

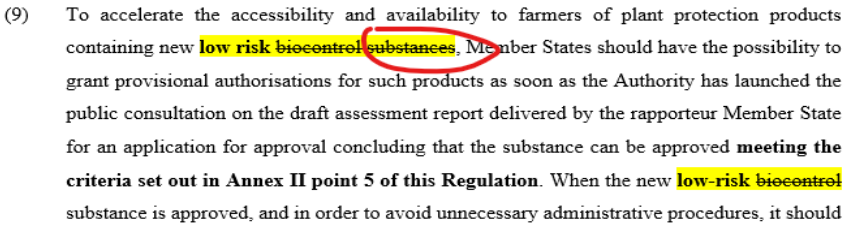
SLOVENSKO

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

- **ST 9) 571/26** (Presidency compromise text)
- **WK 7222/2026** (Presidency explanatory note)

SK comments:

1. Recital (9) - Word "substance" should remain in the text



(9) To accelerate the accessibility and availability to farmers of plant protection products containing new **low risk** ~~biocontrol~~ ~~substances~~, Member States should have the possibility to grant provisional authorisations for such products as soon as the Authority has launched the public consultation on the draft assessment report delivered by the rapporteur Member State for an application for approval concluding that the substance can be approved **meeting the criteria set out in Annex II point 5 of this Regulation**. When the new **low-risk** ~~biocontrol~~ substance is approved, and in order to avoid unnecessary administrative procedures, it should

2. Art. 27a (1) - If the exceptions for low risk active substances listed in letters c) and d) remain, what will be the period for their approval after the end of the assessment and the decision on approval? If unlimited, we agree with the inclusion of these provisions, if not, we propose to delete the text under letters c) and d). We ask the Commission for clarification.
3. Art. 32 - We propose to leave in the text the option for the content of safeners and synergists, if these are classified as low risk.
4. Art. 43a - We do not find the 3-month period as sufficient. We propose to add the option to "stop the clock" if necessary, also for Art 43, the current "standing" proceedings due to Cat 4 studies have no basis in the Regulation.
5. Art. 59 (9) We suggest adding/correcting the text in red. Why should data protection only be applied for the first renewal?

   (9) Data protection shall be granted to test and study reports necessary for the renewal**, targeted reassessment** or review of an authorisation. The period for data protection shall be 30 months from the ~~**first**~~ renewal**, targeted reassessment or review** of the authorisation granted in accordance with Articles 43 **and 43a** in any Member State or from the first conclusion of a review conducted in accordance with Article 44 in any Member State. Paragraphs 1 to 5 of this Article shall apply *mutatis mutandis*.

6. **RED LINE – Art. 37 (5), art. 42 (3) and relevant recital (10a)**

   We cannot agree with the "tacit agreement" provided for in Articles 37 and 42.
   We fundamentally disagree with the form of application of the tacit agreement as it is proposed and, moreover, with the notification obligation for the Member States. This introduces legal uncertainty when issuing decisions on the authorization of plant protection products (we have already sent the justification in previous comments). As a compromise, we can support a voluntary decision by the Member States, the proposal is presented below.

   Art. 37 (5) (and similar art. 42 (3)

‘5. Where the application concerns a plant protection product containing as active substances only ~~biocontrol or~~ low-risk active substances **and** the other Member States concerned have not adopted a decision after 120 days, the authorisation **may** be deemed as having been granted by the Member States**.** ~~**unless such a principle of administrative tacit agreement does not exist in the national legal system of the other Member State concerned**. In such a case **the authorisation is deemed to be granted,** Those Member States concerned shall grant **issue** the authorisation, send it to the applicant and inform of the publication of this information on the authorised plant protection product in accordance with Article 57(1), in particular the authorisation number. **Member States whose the national legal system does not allow the application of tacit approval shall inform the Commission thereof by [*12 months from entry into force of this Regulation*].**~~ Member States which decide to make use of this option shall establish procedures for granting authorisation by tacit agreement and shall inform the Commission thereof.

Recital (10a)

Where mutual recognition is sought for a plant protection product containing only low-risk active substances, provided that they are not expected to present a different level of risk in different Member States or to require risk mitigation measures and that the assessment has already been carried out by another Member State, such recognition may be deemed to have been granted by tacit agreement if no decision is taken within the relevant period, provided that the Member State decides to apply this option in practice. In order to facilitate the application of this provision, Member States shall establish procedures for granting authorisation by tacit agreement and inform the Commission if they opt for this option.

7. **We repeatedly request amendments to Article 53 as follows:**

Article 53

Emergency authorisation

1. By way of derogation from Article 28, a Member State may authorise, for a period not exceeding one growing season for a specific crop/pest/disease combination,

a) the placing on the market and use of plant protection products, not authorised in a member state,
b) the use of authorised plant protection product beyond the scope of existing authorisation,
c) the placing on the market and use of treated seeds or plant propagating material

if such measure appears to be necessary due to danger which cannot be contained by any other reasonable means, taking into account the possible resistance.

2. Emergency authorisation pursuant to paragraph 1 may also apply for the use of the plant protection products for which the conditions of approval of the active substance contained in the plant protection product do not allow authorisation such use pursuant to Article 28.

3. In case of emergency authorisation pursuant of paragraph 2 risk reduction measures and consumer risk assessment shall ensure an acceptable risk to human health and the environment.

4. The Member State concerned shall in 30 days from issuing of emergency authorisation inform the other Member States and the Commission of the measure taken, providing detailed

information about the agronomic situation and any measures taken to ensure consumer and environmental safety.

5. A Member State may grant an emergency authorization for a specific crop/pest/disease based on an emergency authorization issued by another Member State in the same zone, provided that the occurrence of the pest or disease for which the authorization was granted has been confirmed.

6. The Commission may ask the Authority for an opinion, or for scientific or technical assistance.

The Authority shall provide its opinion to the Commission within 1 month of the date of the request.

7. If necessary, a decision shall be taken, in accordance with the regulatory procedure referred to in Article 79(3), as to when and under what conditions the Member State:

(a) may or may not extend the duration of the measure or repeat it; or

(b) shall withdraw or amend its measure.

8. Paragraphs 1 to 6 shall not apply to plant protection products containing or composed of genetically modified organisms unless such release has been accepted in accordance with Directive 2001/18/EC.

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FINLAND

SUOMI

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
Examination of the Presidency compromise texts

ST 9691/26 (Presidency compromise text, BPR)

- Finland notes, that the new compromise text includes significant changes to the previous version.
- We can support proposals for prolonged approval instead of unlimited approvals, inclusion of new recital 34a as well as new addition to Article 13.
- However, the question of selecting active substances for renewal procedure based on new information or safety concerns, remains.
- As far as we see, there are two possibilities.
    - Leaving recital 34 as it was proposed in the first version from last Thursday AND leave the Art 14a in the text but modify it in a way that fits to the principle of prolonged approvals. In this option, including article 14a would be necessary to give the Commission powers to do the selection as intended in the recital 34.
    - Make changes like proposed in the rev1 on the document. In practice, this would mean that we rely on the possibilities to review approvals at any time based on existing Art 15.
- FI has a strong preference to the first option - that is to leave recital 34 and 14a in the text. It would ensure possibilities to review approvals in case new information comes up and enable the Commission to set up a work programme and to request ECHA periodical literature reviews referred to in recital 34.