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From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus X (Food and Feed Safety): follow-up to the AGS of 9 July 2026 – Member States' comments

Delegations will find attached the comments on Omnibus X- Food and feed safety as received following the AGS meeting on 9 July 2026 from **CZ, DK, DE, EE, GR, ES, IT, CY, HU, NL, AT, PL, PT, RO, SI, SK, FI, SE** and a joint wording proposal by **CZ, EE, IT, LV** and **LT**.

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LIMITE

EN

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

DDL 10 July 2026 COB
– MS replies –

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CZECHIA

ČESKO

Regulation (EC) 1107/2009

Art. 3 (34–2)

The Czech Republic does not agree with the proposed amendment to the definition of biostimulants, which it considers inaccurate and misleading, and insists on maintaining the original definition set out in Regulation (EC) No 1107/2009; alternatively, it could support the wording proposed by the Commission.

Justification:

The proposed changes introduce unclear scientific concepts related to plant hormonal regulation (for example, “interfering with plant hormone signalling pathways”), which does not correspond to current scientific understanding, according to which physiological processes are interconnected.

In practice, this could lead to ordinary plant biostimulants or nutrients being classified as plant protection products. This would require an individual assessment of each product, increase the administrative burden, and create a risk of divergent interpretations among Member States. The result would be uncertainty for manufacturers and farmers, as well as the possible withdrawal of products already available on the market. The proposal is therefore contrary to the objective of Omnibus X to simplify legislation.

Art. 27a

The Czech Republic calls for a technical discussion on the new wording of Article 27a of Regulation (EC) No 1107/2009.

Justification:

Article 27a newly expands the criteria that will lead to a limitation of the approval period for active substances. We request an explanation from the Presidency as to why the classification criteria (Carc. 2, Repr. 2, Muta. 2) are explicitly listed.

Art. 53

The Czech Republic calls for a technical discussion on the new wording of Article 53.

Justification:

The new provision proposes the possibility of taking over the assessment of another Member State, which is already possible under the current wording of the Article. We would consider it a step towards simplification and towards enabling a timely response to emergency situations in plant protection if mutual recognition of products authorised under Article 53 were made possible. This

should be optional mutual recognition, i.e. pursuant to Article 40(1)(b). However, this provision should explicitly state that, in the case of such mutual recognition, all conditions laid down in Article 53(1) must be fulfilled.

Regulation (EC) 396/2005

Art. 14

The Czech Republic calls for a discussion on the German proposal to amend Article 14 of Regulation (EC) No 396/2005. The proposal responds to the concerns of a number of Member States and was supported by a significant number of delegations at the meeting on 9 July.

Justification:

From the Czech Republic's perspective, the current wording still does not sufficiently address the concerns of Member States. The proposed changes to the approach to maximum residue levels represent a fundamental systemic change with potentially far-reaching consequences for the agri-food sector, trade, and EU competitiveness. In our view, such changes should not be adopted before a comprehensive impact assessment has been completed, particularly because the current maximum residue levels have already been established on the basis of a scientific assessment and available data. The German proposal removes the Czech Republic's main concerns. It removes the negative effects on bees and groundwater as a condition, thereby returning the proposal to where it belongs, namely solely to the area of human health. It explicitly incorporates into the text the requirement to assess the impact of lowering MRLs, including impacts on trade. This proposal therefore brings the text significantly closer to the Czech Republic's position.

Nařízení (ES) č. 1107/2009

Čl. 3 bod 34–2

Česká republika nesouhlasí s navrhovanou úpravou definice biostimulantů, kterou považuje za nepřesnou a zavádějící, a trvá na zachování původní definice uvedené v nařízení (ES) č. 1107/2009; případně by mohla podpořit znění navržené Komisí.

Odůvodnění:

Navrhované změny zavádějí nejasné vědecké pojmy související s hormonální regulací rostlin (například „zasahování do signálních drah rostlinných hormonů“), což neodpovídá současnému vědeckému poznání, podle něhož jsou fyziologické procesy vzájemně propojené.

V praxi by to mohlo vést k zařazení běžných rostlinných biostimulantů nebo živin mezi přípravky na ochranu rostlin. To by vyžadovalo individuální posouzení každého přípravku, zvýšilo administrativní zátěž a vytvořilo riziko rozdílných výkladů mezi členskými státy. Výsledkem by byla nejistota pro výrobce i zemědělce a také možné stažení výrobků již dostupných na trhu. Návrh je proto v rozporu s cílem Omnibus X zjednodušit právní předpisy.

Čl. 27a

Česká republika požaduje technickou diskusi k novému znění článku 27a nařízení (ES) č. 1107/2009.

Odůvodnění:

Článek 27a nově rozšiřuje kritéria, která povedou k omezení doby schválení účinných látek. Žádáme předsednictví o vysvětlení, proč jsou klasifikační kritéria (Carc. 2, Repr. 2, Muta. 2) výslovně uvedena.

Čl. 53

Česká republika požaduje technickou diskusi k novému znění článku 53.

Odůvodnění:

Nové ustanovení navrhuje možnost převzetí posouzení jiného členského státu, což je možné již podle současného znění článku. Za krok ke zjednodušení a k umožnění včasné reakce na mimořádné situace v ochraně rostlin bychom považovali umožnění vzájemného uznávání přípravků povolených podle článku 53. Mělo by jít o nepovinné vzájemné uznávání, tj. podle čl. 40 odst. 1 písm. b). Toto ustanovení by však mělo výslovně uvádět, že v případě takového vzájemného uznání musí být splněny všechny podmínky stanovené v čl. 53 odst. 1.

Nařízení (ES) č. 396/2005

Čl. 14

Česká republika požaduje diskusi k německému návrhu na úpravu článku 14 nařízení (ES) č. 396/2005. Návrh reaguje na obavy řady členských států a na jednání dne 9. července jej podpořil významný počet delegací.

Odůvodnění:

Z pohledu České republiky současné znění stále dostatečně neřeší obavy členských států. Navrhované změny v přístupu k maximálním limitům reziduí představují zásadní systémovou změnu s potenciálně dalekosáhlými dopady na zemědělsko-potravinářský sektor, obchod a konkurenceschopnost EU. Podle našeho názoru by takové změny neměly být přijaty před dokončením komplexního posouzení dopadů, zejména proto, že současné maximální limity reziduí již byly stanoveny na základě vědeckého posouzení a dostupných údajů.

Německý návrh odstraňuje hlavní obavy České republiky. Odstraňuje negativní účinky na včely a podzemní vody jako podmínku, čímž vrací návrh tam, kam věcně patří, tedy výlučně do oblasti ochrany lidského zdraví. Do textu výslovně začleňuje požadavek na posouzení dopadů snížení MRL, včetně dopadů na obchod. Tento návrh proto významně přibližuje text pozici České republiky.

DENMARK

DANMARK

Relevant documents

- CM 3522/1/26
- WK 9779/2026
- ST 11412/2026

1. Omnibus X: Food and feed safety

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

First round

Guiding question: Do delegations consider that these changes bring a satisfactory balance of simplification with adequate safeguards?

- Denmark appreciates that there have been made important improvements during the negotiation but still finds that there are insufficient safeguards to achieve a satisfactory balance between simplification and protection of the environment and human health.
- Denmark can support the clarification proposed in recital 34 regarding the approval periods for already approved substances as well as the changes to article 14(2), 18a(1) and article 21(1).
- Denmark is very concerned about the addition of 'risk management measures and application techniques to the wording of article 4(1) and 4(3) as technical knowledge. While the use of new precision application techniques is positive, the proposed amendment will lower the bar for approval of active substances and introduce active substances which would not be approved under the current rules, because of unacceptable risks to the environment and human health.

Second round

Guiding question: Do delegations consider that these changes bring sufficient simplification?

- Regarding tacit agreement on mutual recognition, Denmark would prefer reverting to the wording of the fourth compromise proposal, under which mutual recognition by tacit agreement applies to only low-risk active substances.
- Denmark do not support the additions to 33(2)(b), which will make the simplified one-zone approach applicable to all new active substances, not just low-risk active substances. We should promote active substances that are low-risk, but cannot see a justification for giving preferential treatment to substances, only because they are new. New is not necessarily safer or better for human health and the environment, and we need to create incentives for innovation in low-risk substances.
- Denmark is opposed to the one-zone approach suggested in article 33(2)(b) as well as article 40(1)(c), since it may lead to an increase in complexity of the single assessment, a lot of coordination, and more of the assessment being left to the member states.

- Denmark do not support the addition to article 53(1) allowing a Member State to grant an emergency authorisation based on an existing assessment made by another Member State in the same zone without making an individual assessment. Emergency authorizations should only be used in exceptional cases.

Additional remarks on pesticides and biocides (1107/2009 and 528/2012)

- Denmark still supports the compromise proposal from the Presidency where the current principle for renewals of biocidal active substances continues to be maintained.
- Furthermore, Denmark supports that unlimited approvals/authorizations will only apply to low-risk active substances and for the products containing them.
- Denmark still finds the previous changes to article 4(7) unacceptable. It is unacceptable to allow active substances with proven unacceptable risk to human health and environment to be approved for five years.
- Denmark is strongly opposed to the extension of the grace period from 18 months to three years in article 20 as this will negatively affect the protection level.

Additional remarks on MRL (396/2005)

- Denmark acknowledges the efforts to find a compromise but are sceptical about moving forward without a robust impact assessment of the proposed changes.
- Denmark finds it is of importance, that prior to lowering the MRL both a risk assessment of the Authority, and an assessment of the impact on the food and feed chain in the Member States are considered.
- Denmark supports the compromise presented by Germany.

GERMANY

DEUTSCHLAND

DE Compromise Proposal on Maximum Residue Levels Recital (27)

(27) Regulation (EC) No 396/20056 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. On this basis the Commission may, if appropriate, propose amendments to the legal framework, including to Article 14 of Regulation (EC) No 396/2005. 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 **should shall be reconsidered and accordingly** set at the limit of quantification (technical zero), if appropriate based on a prior impact assessment. The decision on setting or lowering MRLs should take into account, in addition to the risk assessment of the Authority, an assessment of the impact on the food and feed chain in the Member States, in compliance with international obligations, in particular the General Agreement on Tariffs and Trade 1994 and the Sanitary and Phytosanitary Measures Agreement.

Article 3

Amendments to Regulation (EC) No 396/2005

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

(...)

Article 14 is amended as follows:

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

–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**, according to the latest available evaluation under Regulation (EC) No 1107/2009 or to a specific evaluation in accordance with Article 43 of **this Regulation** ~~(EC) No 396/2005~~, a MRL ~~that has been set based on a CXL or a GAP implemented in a third country can be revoked and shall be~~ **reconsidered and accordingly** set in accordance with Article 18(1)(b) or Article 16 if considered appropriate in the light of the ~~outcome of an~~ **of this Regulation based on a prior** impact assessment, **taking into account in addition to the risk assessment of the Authority, an assessment of the impact on the food and feed chain in the Member States, in compliance with international obligations, in particular the General Agreement on Tariffs and Trade 1994 and the Sanitary and Phytosanitary Measures Agreement.**

By derogation from the duration foreseen in Article 14(1), 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 or criteria referred to in the first subparagraph.

This paragraph shall not apply to MRLs for 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.’;

Regulation (EC) No 1107/2009

- We would like to thank the Irish Presidency for the compromise text under consideration and explicitly commend their dedicated approach to finding a solution.
- We do not support the fact that the proposal no longer consistently restricts the procedural advantages for product authorization to "low-risk" substances.

Clarification of criteria for targeted reassessment (Article 18a(1)) & Mandating of EFSA to review where necessary (Article 21(1), Recital 15b)

- To what extent is the envisioned mandating of EFSA intended to differ from the Commission's existing possibility under Article 21(2) to request EFSA's assistance? Is this intended to introduce an additional special review? What criteria would apply to it? We are concerned that this could lead to legal uncertainty and protracted procedures.

Emergency derogations (Article 53(1))

- We view the proposal for a simplified emergency authorization with a degree of skepticism, as emergency authorizations must always be the response to a specific, acute regional emergency and must not become a blanket authorization through the back door. At the same time, however, we recognize the underlying intent to reduce red tape: if the exact same emergency is demonstrably present within the same climatic zone, national authorities should be free to rely on already evaluated data in order to react promptly and unbureaucratically in times of crisis.

One-zone approach for low-risk substances (Article 33(2)(b))

- We favor the one-zone approach exclusively for greenhouse applications, post-harvest and seed treatments, the control of listed harmful organisms, and low-risk substances.

Mutual recognition based on one zone approach for newly approved substances (Article 40(1)(c))

- We favor the one-zone approach exclusively for greenhouse applications, post-harvest and seed treatments, the control of listed harmful organisms, and low-risk substances.
- Upon closer examination, we maintain concerns regarding the proposals for the demarcation between biostimulants and plant growth regulators. We see the necessity of keeping plant

growth regulators within the scope of Regulation (EC) No 1107/2009. In particular, the enumeration of the modes of action in Recital 6 could inadvertently exclude potential biostimulants. If necessary, this demarcation should be discussed further with Member State experts in order to establish a proper and regulatorily secure definition without unintentionally altering the legal scope of Regulation (EU) No 2019/1009. At this juncture, the existing definition for biostimulants pursuant to Article 47 of Regulation (EU) 2019/1009 should therefore be maintained.

Proposal: Deletion of Recital 6, Article 2(a), and Article 3(b).

- Regarding the definition of greenhouses in Article 3, point 27, we would like to point out that while a structure that prevents the escape of plant protection products into the environment is beneficial from an environmental protection perspective, such a closed structure poses a higher risk to operator health. Furthermore, the degradation behavior of active substances in such environments differs drastically from open-field conditions. The proposed definition, however, completely overlooks this conflict of objectives between environmental protection and operator safety. A differentiated definition that clearly distinguishes between open and closed greenhouses would therefore be more appropriate.

Proposal: Deletion of "27. 'greenhouse' means a walk-in, static, closed place of crop production with a usually translucent outer shell, and which effectively restricts the release of plant protection products into the environment. Open tunnel structures are not considered greenhouses.; For the purpose of this Regulation, closed places of plant production where the outer shell is not translucent (for example, for production of mushrooms or witloof) are also considered as greenhouses."

ESTONIA

EESTI

Omnibus X: Food and feed safety

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 text

First Round

Article 4(1) and (3)

Estonia cannot support the proposed amendment, as it introduces additional criteria to be taken into account instead of simplifying the approval process.

Article 4(7)

Estonia maintains its position that a socio-economic impact assessment criterion should be included for both active substances and plant protection products. Given the continuous loss of available plant protection products from the market, farmers are left with an increasingly limited toolbox to protect crops and safeguard food security.

A drafting proposal submitted by several Member States is attached in a separate document.

Article 14(2)

Estonia could accept this as a compromise. However, Estonia continues to favour approvals without a fixed expiry date, as originally proposed by the Commission, since this would constitute a significant simplification and reduce administrative burden.

Article 18a(1)

Estonia has no specific comments on the proposed clarification and does not object to specifying that one or more of the listed criteria may be sufficient to trigger a targeted reassessment.

Article 21(1) and Recital 15b

The obligation for EFSA to assess available scientific literature and monitoring data on approved active substances is already, in substance, reflected in the current Regulation. Estonia considers that this amendment should not diminish the effect of the amendment introduced in Article 36 regarding the definition of the most recent assessment, namely that this refers to the latest assessment carried out at EU level.

Further clarification is needed as to why this additional provision is necessary and what objective it is intended to achieve.

Article 27a(2)(b)

Estonia would welcome clarification on the rationale for establishing a list of already approved active substances whose approvals will not be renewed following the entry into force of this proposal. Given the already very limited availability of plant protection products, further restricting farmers' toolbox raises concerns.

Article 27a and Article 81a

Estonia supports the proposed amendments.

Recital 34

Estonia has a positive view of the proposed recital.

Second Round

Article 33(2)(b) and Recital 10

Estonia enters a scrutiny reservation.

The proposed text is unclear, and the recital creates additional ambiguity. The wording could be interpreted as extending the one-zone approach to all new active substances rather than limiting it to low-risk active substances.

Further clarification is needed as to whether the Presidency intends to apply the one-zone approach only to low-risk active substances, whereby the assessment would be carried out by a single Member State, as suggested in Recital 10.

Article 37(5) and Article 42(3)

Estonia does not object to the proposed amendments. However, these changes do not appear to contribute to simplification.

Article 40(1)(c)

The proposed amendment is unclear. It is not evident how an authorisation could be granted for a plant protection product containing active substances that have not yet been approved.

Article 53(1)

Estonia has no position at this stage, as this is a new proposal requiring further assessment.

While the proposal is of interest, reopening this provision could ultimately result in additional restrictions, further limiting the already constrained toolbox available to farmers for addressing emerging plant protection challenges.

Regarding the **MRL Regulation**, as stated at the meeting Estonia can support Germany proposal, we find it creates the necessary clarity.

Since the proposed changes to 396 are fundamental, it is important that an impact assessment is carried out before such changes are made. It is therefore appropriate to also remove the part concerning bees and groundwater from the draft, which is intended as a temporary solution.

GREECE

ELLÁDA

1) REGULATION (EC) 1107/2009

We welcome the efforts of the Presidency to address the concerns expressed by Member States and to identify balanced compromise solutions on a number of key issues discussed during the negotiations.

In addition to the amendments commented upon in the attached document, we would also like to reiterate a number of comments previously submitted and which we consider particularly important for the further development of the discussions.

Our comments focus on a number of key issues that, in our view, are fundamental to preserving the scientific basis, effectiveness and workability of the current regulatory framework. In particular, we stress the need to facilitate farmers' access to new safe and effective active substances, while maintaining robust assessment standards and ensuring that any simplification measures remain proportionate and scientifically justified.

We also reiterate our concerns regarding proposals that could weaken the zonal authorisation system, extend simplified procedures beyond genuinely low-risk plant protection products, or introduce new mechanisms whose practical implementation, workload implications and added value have not yet been sufficiently demonstrated. Furthermore, we consider it important to preserve Member States' responsibilities in areas such as emergency authorisations and to avoid creating additional administrative burdens without clear benefits.

Recital (4)

The current wording has to be simplified to indicate clearly that. The fundamental objective is not simply to increase the availability of a particular category of plant protection products, but to ensure that farmers have timely access to new active substances that are safe, effective and capable of addressing the increasingly serious plant protection challenges they face. The number of available solutions has already declined significantly and is expected to continue decreasing rapidly as more existing active substances are withdrawn. Therefore, the legislative framework should focus on facilitating innovation and accelerating access to new, safe active substances that provide effective crop protection while maintaining a high level of protection for human health and the environment.

Proposed redrafting:

In order to reduce farmers' dependency on older plant protection products and in line with the objectives of the Communication A Vision for Agriculture and Food, access to innovative plant protection products should be facilitated by improving the availability of products containing new active substances including biocontrol active substances that provide safe and effective solutions to current and emerging plant protection challenges. The regulatory framework should therefore facilitate the timely authorisation and market access of plant protection products containing new active substances, that have not previously been approved in the Union [at the date of entry into force of this Regulation] while ensuring a high level of protection for human health and the environment.

Recital (7)

Following the amendment proposed in Recital 4, priority should not be limited to biocontrol active substances alone. Farmers need timely access to all innovative active substances that provide safe and effective solutions to current and emerging plant protection challenges.

Proposed redrafting:

For the same purpose, the evaluation of applications for the approval of **new active substances, including biocontrol active substances**, and for the authorisation of plant protection products

containing only low-risk active substances should be given priority to ensure timely crop protection from existing pests and diseases.

Recital (9)

The same applies also in the last paragraph of this recital

Proposed redrafting:

As regards plant protection products containing as active substances only **of new active substances, including** biocontrol substances, those that can benefit from the provisional authorisation are those which meet the low-risk criteria set out in Annex II, point 5, of this Regulation.

Recital (10)

We cannot support the proposed approach and consider it a red line.

As we have repeatedly underlined during the discussions, the authorisation of a plant protection product in the European Union cannot be based on the concept of a single evaluation considering EU as one authorisation zone. Significant differences exist between Member States between zones, even within the same zone with regard to environmental and agronomic conditions, pest pressure, cropping practices and, above all, the efficacy of plant protection products. These differences require an appropriate scientific assessment at zonal level and cannot be adequately addressed through a single zonal evaluation.

Furthermore, with the proposed extension of the scope beyond low-risk active substances, we cannot support the simplified procedure. Such an approach could compromise the quality of the assessment and does not adequately reflect the substantial differences between Member States within each authorisation zone.

For these reasons, we cannot support the proposed amendment.

Recital (15b)

We do not clearly understand the purpose or the added value of the final sentence introducing the possibility for the Commission to request the Authority to review relevant scientific literature and monitoring data on approved active substances.

Regulation (EC) No 1107/2009 already contains appropriate provisions to address situations where new scientific or technical information becomes available after the approval of an active substance. In particular, it provides mechanisms for the review, amendment or withdrawal of approvals where there are indications that the approval criteria may no longer be fulfilled.

We therefore consider that the current legal framework is sufficient to ensure that new evidence is appropriately assessed whenever concerns arise regarding an approved active substance.

Article 3 point 17 “for plant protection products containing as active substances only low-risk active substances, the zone means all zones defined in Annex I”

We consider that the presence of low-risk active substances alone should not be sufficient to justify the application of this approach.

In our view, such provisions should apply only to plant protection products that are themselves classified as low-risk plant protection products in accordance with Regulation (EC) No 1107/2009. Consequently, both conditions should be fulfilled: the product should contain only low-risk active substances and the plant protection product itself should meet the criteria for classification as a low-risk product.

This principle should be applied consistently throughout the text. In several provisions, reference is made to plant protection products containing low-risk active substances without specifying that the plant protection products themselves must also qualify as low-risk products. We consider that this should be clarified in the final text. Whenever specific advantages, simplified procedures or derogations are granted on the basis of the low-risk status, eligibility should be limited to plant protection products that are themselves authorised as low-risk plant protection products and not merely to products containing low-risk active substances.

Otherwise, we would not be in a position to support the proposed approach, as it could extend the benefits of the simplified regime to products that have not been assessed and recognized as low-risk at product level.

‘Article 14 Renewal of approval point 2

We would welcome further clarification regarding the final sentence stating that *"A shorter period may be established in accordance with Article 6(j)."*

It is not clear how this provision is intended to operate in practice, particularly in the context of the proposed unlimited approval period for low-risk active substances. The relationship between an unlimited approval and the possibility of establishing a shorter approval period under Article 6(j) is not sufficiently explained, and it is therefore difficult to understand the practical effect and added value of this provision.

We would therefore appreciate further clarification on the intended scope and application of this sentence.

As already indicated in our previous comments, we acknowledge the objective of reducing the administrative burden through longer approval periods and recognize the potential benefits of introducing unlimited approvals for low-risk active substances. However, we have also expressed reservations regarding the practical implementation of the proposed targeted reassessment system, as several key aspects remain unclear. At this stage, we are not convinced that the proposed system would provide a clear added value over the current renewal framework, particularly considering that the extension of approval periods under the existing system already contributes significantly to reducing the administrative burden. In this context, further clarification on the purpose and operation of the proposed provision is necessary.

Article 18a Targeted reassessment of active substances

As we have already stated in our previous comments, we support the objective of reducing the administrative burden and recognize that extending approval periods, including the introduction of unlimited approvals for low-risk active substances, could contribute to this objective and allow competent authorities to focus resources on the assessment of new active substances.

However, we remain unconvinced that the proposed targeted reassessment system would provide a clear added value compared with the existing renewal framework. The current system is well-established and its procedures are clearly defined, whereas the proposed targeted reassessment introduces a new mechanism whose practical implementation remains unclear. In particular, further clarification is needed regarding the criteria for selecting substances for reassessment, the frequency of reassessments, the workload for Member States and the Commission, and the overall operation of the system.

At this stage, we consider that extending approval periods within the existing framework already achieves the objective of reducing the administrative burden to a significant extent. Therefore, further discussion is needed to demonstrate that the proposed targeted reassessment system would be more efficient, predictable and proportionate than the current renewal regime.

In Article 21, paragraph 1,

We cannot support this proposal.

Regulation (EC) No 1107/2009 already contains appropriate provisions to address situations where new scientific or technical information becomes available after the approval of an active substance. In particular, it provides mechanisms for the review, amendment or withdrawal of approvals where there are indications that the approval criteria may no longer be fulfilled.

We therefore consider that the current legal framework is sufficient to ensure that new evidence is appropriately assessed whenever concerns arise regarding an approved active substance.

Article 23 Approval criteria for basic substances

(b) the use of the basic substance in a product consisting of the basic substance and of, as applicable, a simple diluent, other basic substances or substances necessary to stabilize the product. Such products shall not contain any co-formulants listed in Annex III;

Basic substances constitute a specific regulatory category based on the principle that they can be used without undergoing the full approval and authorisation procedures applicable to plant protection products. Allowing the addition of stabilisers would place in the market products that have not been specifically assessed within the framework of the basic substance approval and whose function is comparable to that of co-formulants used in plant protection products.

Such an approach would create uncertainty regarding the composition of products placed on the market and could result in products containing additional substances that have not been subject to an appropriate evaluation. In our view, this would go beyond the original concept and intended scope of basic substances and could undermine the distinction between basic substances and authorised plant protection products.

For these reasons, we cannot agree with the proposed wording and consider that products based on basic substances should be limited to the approved basic substance itself and, where appropriate, a simple diluent.

Article 30 Provisional authorisations

Regarding Article 30 on provisional authorisations, we consider that it should be made explicit that this procedure applies only to plant protection products that are themselves low-risk plant protection products and not merely to products containing low-risk active substances. The low-risk status should be demonstrated both at active substance level and at product level in order for the relevant provisions to apply.

Subject to this clarification, we could accept the proposed approach, particularly considering that Member States retain the possibility not to apply the provisional authorisation procedure.

Nevertheless, we would like to note that we remain uncertain as to whether the expected benefits justify the introduction of an additional administrative procedure. In our view, its practical added value and implementation should be carefully assessed.

Article 32 Duration

Authorisations shall be valid for an unlimited time if the plant protection product concerned contains as active substances only low-risk active substances with unlimited approval periods.

We consider that the wording should be clarified to ensure that unlimited authorisations are granted only to plant protection products that are themselves authorised as low-risk plant protection products and not merely to products containing low-risk active substances.

This clarification is essential to ensure consistency throughout the text and to avoid extending the benefits associated with the low-risk regime to products that have not been assessed and recognized as low-risk at product level.

Article 33, paragraph 2, point (b)

Reiterating recital 10 comments

We cannot support the proposed approach and consider it a red line.

As we have repeatedly underlined during the discussions, the authorisation of a plant protection product in the European Union cannot be based on the concept of a single evaluation considering EU as one authorisation zone. Significant differences exist between Member States between zones, even within the same zone with regard to environmental and agronomic conditions, pest pressure, cropping practices and, above all, the efficacy of plant protection products. These differences require an appropriate scientific assessment at zonal level and cannot be adequately addressed through a single zonal evaluation. Such an approach could compromise the quality of the assessment and does not adequately reflect the substantial differences between Member States within each authorisation zone.

For these reasons, we cannot support the proposed amendment.

Article 40 Mutual recognition

We cannot support the proposed approach and consider it a red line.

See comments for article 33.

Article 43a Targeted reassessment of authorisation

Our comments on Article 43a are closely linked to our reservations regarding Article 18a and the introduction of the targeted reassessment system for active substances. As already indicated, we are not yet convinced of the added value and practical implementation of this new mechanism.

Consequently, the necessity and usefulness of Article 43a depend largely on whether the approach set out in Article 18a is ultimately retained.

(33a) In Article 53, paragraph 1, a third subparagraph is inserted:

We cannot support this provision and consider it a red line.

The purpose of the proposed amendment is unclear, and we do not understand its legal basis or the problem it is intended to address. Further clarification is needed regarding its practical application and its relationship with the existing provisions of Article 53 of Regulation (EC) No 1107/2009.

Article 53 provides for the granting of emergency authorisations by each Member State on the basis of its own assessment of the specific emergency situation and the particular national circumstances. The decision of one Member State cannot and should not influence or serve as the basis for the decision of another Member State, even where both belong to the same zone. The proposed wording introduces legal uncertainty as to the respective responsibilities of Member States and could undermine the principle that emergency authorisations remain a national competence based on a case-by-case assessment. As currently drafted, we do not see the added value of this provision and cannot support its inclusion.

Article 59 Data protection

The proposed procedure cannot be supported at Member State level, as it would require authorities to verify any data protection claim made by the applicant at the level of each individual test and study report. Similar approaches have proven extremely difficult to implement in the past and we see no indication that such a system would function effectively in practice.

Regarding the proposed EU database, we recognize that, in principle, the creation of a central database for protected studies could be a useful initiative. However, we have serious concerns about its practical implementation. The proposal would place an additional administrative burden on Member States, which would be required to enter and maintain information on individual studies within strict

deadlines. Furthermore, there is considerable uncertainty regarding the development, availability and operational readiness of such a database.

For these reasons, we maintain serious reservations on the proposed provisions.

2) REGULATION (EC) 2017/625 (OCR) (PLANT HEALTH ISSUES)

With regard to (a) the provisions on Plant Health Sector and (b) the use of the Common Health Entry Document (hereinafter CHED), we can support the Presidency's compromise text.

SPANISH POSITION TO PDCY COMPROMISE TEXT (11412/26)

- REGULATION 1107/2009

The critical aspects of the proposal, which should constitute red lines for Spain, are as follows:

- 1) **Prioritisation of biocontrol substances and products containing low-risk active substances:** We support the prioritisation of innovation, but not solely for biocontrol/low-risk active substances. Our farmers must have access to the most innovative, sustainable, and genuinely effective plant protection tools in the shortest possible timeframe. However, the Commission's proposal focuses on the approval of biocontrol active substances, despite evidence that these are not always low-risk nor, in many cases, effective. Therefore, new solutions must be prioritised regardless of whether their origin is biological or not. Additionally, we consider that prioritising biocontrol/low-risk solutions in this manner could lead to a shortage of "traditional" plant protection products, which remain essential as a last resort within integrated pest management (IPM).

SPECIFIC REDACTION PROPOSAL FOR THIS POINT:

- Modification in recital 7:

*(7) For the same purpose, the evaluation of applications for approval of ~~new such biocontrol~~ active substances, **never approved before at European level**, and for the authorisation of plant protection products containing ~~them only low-risk active substances~~ should be given priority to ensure timely crop protection from existing pests and diseases.*

- Modification of article 5:

(4) Article 5

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

- Modification of article 7, with two redaction alternatives:

(5) in Article 7, paragraph 1 is replaced by the following:

(1) [...]

By way of derogation from the first subparagraph, applications for the approval of ~~biocontrol substances~~ active substances never before approved at European level shall ~~may~~ be submitted to the Authority which shall assume the duties of the rapporteur Member State.;

Or

(5) in Article 7, paragraph 1 is replaced by the following:

(1) [...]

By way of derogation from the first subparagraph, applications for the approval of ~~biocontrol substances~~ active substances never before approved at European level shall ~~may~~ be submitted to the Authority which shall assume the duties of the rapporteur Member State. For biocontrol active substances the applications may be submitted to the Authority, which could assume the duties of the rapporteur Member State;

- Modification article 11, with two alternatives:

(6) Article 11 is amended as follows:

(a) ~~the following paragraph 1a is added:~~

~~'1a. The rapporteur Member State shall give priority to the assessment of applications for approval of biocontrol substances.~~

Or

(6) Article 11 is amended as follows:

(a) the following paragraph 1a is added:

'1a. The rapporteur Member State shall give priority to the assessment of applications for approval of ~~biocontrol~~ active substances never before approved at European level.

- Modification article 37.6, with two redaction alternatives:

(23) ~~New in Article 37, the following paragraphs 5, 6 and 7 are added to Article 37:~~

~~6. The Member State examining the application shall give priority to the processing of applications for plant protection products containing as active substances only biocontrol low risk active substances.~~

or

~~(23) New in Article 37, the following paragraphs 5, 6 and 7 are added to Article 37:~~

~~6. The Member State examining the application shall give priority to the processing of applications for plant protection products containing as active substances only **biocontrol** **low-risk** active substances **never before approved at European level.**~~

- 2) **Target reassessment:** Articles 18a (for active substances), 43a (for products): the so called “targeted reassessment”. The new Article 18a and its targeted reassessment of selected active substances—together with the review of products containing them (Article 43a)—generate additional workload. Under the current framework, the workload and timelines for substance/product reviews are clearly defined. However, the scope, timing, and added burden of the targeted reassessment under Article 18a remain undefined, rendering it impossible to guarantee our capacity to accommodate this new workload.

The purported reduction in administrative burden resulting from the unlimited approval of low-risk active substances—and the absence of review for authorisations of products containing them—is debatable. In practice, few active substances are approved without data gaps, critical areas of concern, or other uncertainties, meaning very few would qualify for unlimited approval.

From the Spanish perspective, this undermines the proposal’s alleged simplification.

Since these two new articles were introduced to accommodate the comments of Member States who were dissatisfied or worried about the unlimited approvals initially proposed (for active substances that were neither Candidates for Substitution nor approved as a result of the exception in Article 4.7 or with other problems detected during the renewal/approval), we believe that, as unlimited approvals are now limited to low-risk substances, it is no longer necessary to maintain this reassessment work program. Furthermore, the safeguards for the protection of human and animal health and the environment will not be diminished because we always have Article 21 to review approvals should there be any indication of a problem.

SPECIFIC REDACTION PROPOSAL FOR THIS POINT:

- Withdraw articles 18.a y 43.a

~~**(11) A new Article 18a is inserted:**~~

~~Article 18a Work programme for Targeted reassessment of active substances~~

- ~~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, still 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 be based on the same criteria as laid down in Article 18(1) take into account one or more of the following: information notified by authorisation 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, or and may take into account requests from Member States.~~
- ~~2. The implementing acts referred to in paragraph 1 shall:
(a) list the active substances concerned;
(b) list the rapporteur and co-rapporteur Member States, or the Authority if applicable;
(c) set out the scope of the targeted reassessment for the active substances concerned, and indicate the specific data requirements that apply and, where relevant, the guidance documents and/or scientific opinions that shall be used; and
(d) set deadlines for the submission of the required information for the active substances concerned that allow sufficient time for the generation of the necessary data and the submission of the information.~~
- ~~3. Where the Commission concludes that compliance with the relevant approval criteria covered by the targeted reassessment is demonstrated, it shall adopt an implementing act, confirming the approval, where applicable with conditions and restrictions in accordance with Article 6, in accordance with the procedure referred to in Article 79(3).~~
- ~~4. Where the information referred to in paragraph 2 point (d) has not been provided within the time period established, the Commission shall adopt an implementing act withdrawing the approval in accordance with the procedure referred to in Article 79(3). Where the Commission concludes that the approval criteria covered by the targeted reassessment are no longer satisfied, it shall adopt an implementing act withdrawing the approval in accordance with the procedure referred to in Article~~

~~79(3). In case the derogation set out in Article 4(7) applies, that implementing act may amend the approval.~~

~~5. Articles 13(4), 17 and 20(2) shall apply.;~~

~~And~~

~~(30b) The following Article 43a is inserted:~~

~~'Article 43a~~

~~Targeted reassessment of authorisation~~

~~1. — Following confirmation of the approval of an active substance, safener or synergist in accordance with Article 18a, an authorisation for a plant protection product containing such substance(s) shall undergo targeted reassessment upon application to verify whether the authorisation still meets the requirements of Article 29.~~

~~2. — Within 3 months from the confirmation of the approval of a substance in accordance with Article 18a, the authorisation holder shall submit the application and the following information to allow for a targeted re-assessment of the authorisation:~~

~~(a) a copy of the authorisation of the plant protection product;~~

~~(b) any new information required as a result of the amendments in data requirements or criteria assessed under Article 18a;~~

~~(c) any information required to demonstrate that the plant protection product meets the requirements set out in the Regulation confirming the approval of the active substance, safener or synergist contained therein;~~

~~(d) a report on the monitoring information, where the authorisation was subject to monitoring.~~

~~3. Member States shall check compliance of the plant protection products containing the active substance, safener or synergist concerned with any conditions and restrictions provided for in the confirmation of the approval in accordance with Article 18a.~~

~~The Member State referred to in Article 35 within each zone shall coordinate the compliance check and assessment of the information submitted for all Member States within that zone.~~

~~4. Member States shall decide on the confirmation of the authorisation of a plant protection product at the latest 12 months after the confirmation of the approval of the active substance, safener and synergist contained therein in accordance with Article 18a.~~

~~5. Where the information referred to in paragraph 2 of this Article has not been provided within 3 months of the confirmation of the approval of an active substance, safener or synergist in accordance with Article 18a, the Member State shall withdraw the authorisation. Article 46 shall apply.²~~

- 3) **Data protection (Article 59.6 a and b):** Regarding data protection, we consider that these provisions will significantly undermine innovation by undertakings, as their rights are not sufficiently protected—particularly in the case of minor uses. Furthermore, they will impose an additional administrative burden on Member States, which are required to upload the relevant information to the future EU platform within a maximum period of three months. This new obligation reinforces the perception that the Commission’s proposal does not genuinely pursue simplification but instead introduces further requirements and tasks for Member States.

SPECIFIC REDACTION PROPOSAL FOR THIS POINT:

- Withdraw all modification included in the Omnibus for article 59:

(34) In Article 59 is replaced by the following:

‘Article 59

Data protection

- ~~1. Test and study reports shall benefit from Union-wide data protection under the conditions laid down in this Article.~~
- ~~2. Data protection may be granted to test and study reports concerning the active substance, safener or synergist, adjuvants and the plant protection product as referred to in Article 8(2) when they are submitted to a Member State by an applicant for authorisation under this Regulation, (‘the first applicant’), provided that those test and study reports were:

(a) necessary for the authorisation or for an amendment of the authorisation in order to allow the use on another crop; and

(b) certified as compliant with the principles of good laboratory practice or of good experimental practice.~~
- ~~3. Data protection shall be granted to the test and study reports referred to in paragraph 2 where the first applicant has requested it at the time of submitting the dossier and has provided to the Member State concerned, for each test or study report, the information referred to in point (f) of Article 8(1) and in point (d) of~~

- ~~Article 33(3) as well as confirmation that a period of data protection under this Regulation has never been granted anywhere in the Union.~~
- ~~4. If the first applicant does not request data protection to be granted for a test or study report submitted for the first time in a dossier under this Regulation, it shall not be data-protected and it could be used for the benefit of any subsequent applicants.~~
- ~~5. Where a test or study report is protected, it may not be used by any Member State for the benefit of other applicants for authorisation of plant protection products, safeners or synergists and adjuvants, except as provided in Article 62 or in Article 80, or where:~~
- ~~(a) the applicant has submitted a letter of access; or~~
- ~~(b) any period of data protection granted for the test and study reports under this Regulation has expired.~~
- ~~6. The period of data protection shall be 10 years starting from the date of the authorisation in the first Member State granting an authorisation based on a dossier including the test or study report. That period is extended to 13 years for plant protection products covered by Article 47.~~
- ~~6a. The Commission shall set up and maintain an EU database enabling the registration and verification of the protected tests and study reports submitted under this Regulation. The database shall be publicly accessible.~~
- ~~6b. Member States shall enter the relevant information concerning the protected tests and study reports into the database referred to in paragraph 6a within three months from the date on which the relevant decision becomes final.~~
- ~~7. The period of data protection shall be extended by three months for each extension of authorisation for minor uses on a different crop/pest combination as defined in Article 51(1), except where the extension of authorisation is based on extrapolation, if the applications for such extensions are made by the authorisation holder at the latest five years after the date referred to in paragraph 5.~~
- ~~8. The same data protection rules as for the first authorisation shall also be granted to test and study reports submitted by third parties for the purpose of extension of authorisation for minor uses as referred to in Article 51(1).~~
- ~~9. Data protection shall be granted to test and study reports necessary for the renewal, reassessment or review of an authorisation. The period for data protection shall be 30 months from the first renewal of the authorisation granted in accordance with Article 43. Articles 43 and 43a in any Member State, or from the first confirmation~~

~~of the authorisation granted in accordance with Article 43a in any Member State, or from the first conclusion of a review conducted in accordance with Article 44 in any Member State. The first to fifth Paragraphs 1 to 5 of this Article shall apply mutatis mutandis.~~

~~10. The total period of data protection may not exceed 13 years. For plant protection products covered by Article 47 the total period of data protection may not exceed 15 years.~~

~~11. Detailed rules for the implementation of this Article may be established in accordance with the procedure referred to in Article 79(3).;~~

- REGULATION 1831/2003

Spain could accept the latest text presented at the AGS meeting on 9 July with regard to the amendments to Regulation (EC) No 1831/2003.

Nevertheless, Spain supports the comment made by Austria during the meeting, that Article 16(2)(b) runs counter to the objective of simplification.

We have recently received comments from the sector on this provision and, after analysing them, we have reached the same conclusion.

We regret not having raised this issue at an earlier stage.

In our view, and in line with Austria's position, the obligation to indicate the manufacturer on the label, where it differs from the operator responsible for the labelling, merely creates additional administrative burdens without providing any tangible benefits.

This information is not required under the current legislation, and its absence has not resulted in any reduction in the safety or traceability of products placed on the EU market.

ITALY

ITALIA

Please find below Italy's comments with reference to the Irish Presidency's compromise proposal contained in document st11412/26 and, in particular, to the amendments concerning Regulation EC 1107/2009.

1. We are very pleased that a reference to risk management measures and enforcement techniques has been included in Article 4(1) and (3). We attach the utmost importance to this provision. This amendment recognises the role of safeguard played by the most modern technologies – reference is made to precision farming techniques - to minimise the impact on the environment of the active substances. In addition, this improvement ensures consistency with overarching European policies on innovation.
2. More broadly, we regret that in the current compromise most benefits continue to be in favour of low-risk substances. We would have preferred to see a comparable level of ambition extended to conventional substances and products. That being said, we consider this text to represent the absolute floor, below which we cannot support any further dilution of the simplification measures.
3. We believe that the amendment introduced to Article 53(1) represents a step in the right direction, ensuring greater responsiveness in phytosanitary emergency situations and providing meaningful simplification for Member States and operators alike. We therefore thank the Presidency for introducing this key element, which remains a political priority for our delegation. Consequently, it is essential for us that emergency derogations remain part of the simplification package, as the time factor in phytosanitary emergencies is often decisive to ensure the continuity of agricultural production and effectively address farmers' needs. In our view, this does not lower the level of protection but rather makes it possible to avoid the duplication of administrative procedures and to facilitate a more timely and balanced response within the internal market. While we would have preferred more explicit and ambitious language, in a spirit of compromise, we can support the current wording.

At the same time, we would like to signal at this stage that Italy cannot grant the same flexibility to other parts of the Omnibus X Simplification Package. This applies, in particular, to any attempt to reopen the balance achieved in COREPER on 27 May regarding maximum residue levels of pesticides (MRLs). The current wording already represents a major compromise for Italy; any potential weakening of the text corresponds to a red line.

Cyprus interventions on the AGS meeting on 9 July for OMNIBUS X

First round

From Cyprus' perspective, and in the spirit of compromise, we can support the amendments proposed by the Irish Presidency, in regarding:

- the risk management measures;
- the possibility of shorter renewal periods where there are uncertainties;
- the clarification of the criteria for targeted reassessments;
- the mandate for EFSA to carry out reviews where necessary;
- the removal of the delayed application; and
- the alignment of the approval periods for already approved biocidal active substances with the new approval durations.

We consider that these changes bring a satisfactory balance of simplification.

Second round

Overall, we consider that most of the amendments in the proposed text are moving in the right direction and can deliver meaningful simplification.

However, we still have **serious reservations about the wording on the derogations for emergency authorisations under Article 53**, as it leaves room for different interpretations. We are concerned that this could lead to inconsistent application and, potentially, to an abuse of the derogation. We would like to recall that Article 53 establishes an exceptional derogation, which may only be applied in duly justified emergency situations and under the strict conditions laid down in the Regulation. Any amendment that could be interpreted as broadening the scope of this derogation would risk undermining the high level of protection of human health and the environment that Regulation (EC) No 1107/2009 is intended to ensure.

We should therefore exercise particular caution when introducing any changes to this provision. The proposed wording, whereby *"another Member State from the same zone may grant the same emergency authorisation based on that detailed information,"* could be interpreted as allowing Member States to rely on another Member State's assessment without independently verifying that the exceptional circumstances required by Article 53 are genuinely met in their own territory.

If a Member State authorises the use of products containing hazardous substances in the absence of a genuine emergency or without sufficient justification of the specific threat, the consequences may extend beyond its own borders, creating unnecessary risks to human health, biodiversity and the environment. The exceptional nature of Article 53 should be fully preserved and each Member State

will remain responsible for verifying that all legal conditions for granting an emergency authorisation are satisfied.

I would like to briefly share the approach we follow in Cyprus. Requests for emergency authorisations are examined by a dedicated committee, which assesses each application against the criteria set out in the Commission's SANTE guidance document on emergency situations under Article 53 of Regulation (EC) No 1107/2009.

In addition, the committee takes into account a number of national criteria, including:

- whether an application has been submitted through the mutual recognition procedure for an authorisation granted by another Member State in the same southern zone
- the regulatory status and evaluation history of the active substance at EU level, for example whether it is approved, withdrawn or still under assessment
- the relevance of the request in the context of Integrated Pest Management measures under the Sustainable Use Directive
- the impact on risk, taking into account Harmonised Risk Indicator 2 and
- the specific agricultural, environmental, economic and social conditions in Cyprus.

Because all these elements need to be considered together, every request under Article 53 is assessed on a case-by-case basis.

Different Member States within the same zone may have authorised alternatives available to address the same plant health problem, and therefore they might not need to provide a derogation.

For this reason, we believe that the fact that another Member State in the same zone has already granted an emergency authorisation could certainly be considered as an additional criterion during the assessment. However, we think it should not be included in the legal text, as proposed in the compromise, or the proposed text could be changed for better clarity.

HUNGARY

MAGYARORSZÁG

Hungary acknowledges the efforts of the Irish Presidency to find a balanced approach between the different views of the Member States on the proposed amendment of Regulation (EC) No 1107/2009.

However, we would like to stress that our common interest is to create rules that aim for real simplification to the greatest extent possible.

Background:

The Cyprus Presidency compromise proposal set out a concept for the application for the issuance or amendment of a pesticide authorisation under Article 33(2)(b) that only a single Member State needs to be invited to carry out an evaluation for products containing low-risk active substances already on the market, after which the authorisation will apply to all zones of the entire EU.

The latest Irish Presidency proposal would extend this simplification of the evaluation to all newly developed active substances, not just to low-risk active substances.

A further amendment appears in the proposal to simplify Article 40(1)(c), according to which it is sufficient that one selected Member State carries out the evaluation of all newly developed active substances within the framework of the mutual recognition procedure, regardless of zones, for the entire EU, and not only for products containing biological or low-risk active substances.

In this context, we would like to ask the following:

In the case of Regulation (EC) No 1107/2009, some questions have arisen regarding the proposed text, for which we would like to seek clarification.

Our question is that the benefits of simplifying the evaluation of plant protection products would be applicable to

- all newly developed active substances, regardless they are of biological, low-risk or chemical origin,
- while in the case of active substances already on the market, only the evaluation of products containing low-risk active substances is simplified?

Please clarify this.

NETHERLANDS

NEDERLAND

NL comments follow-up to the AGS of 9 July – Food & Feed

Regulation 396/2005

With regards to Regulation 396/2005, the Netherlands has some serious concerns. As indicated in several Council Working Groups and the Permanent Representatives Committee on 27 May 2026, these concerns regard the Presidency Proposal amending Article 14 paragraph (2). From our point of view, the preferred way forward would still be to refrain from any major changes of the current procedures in this Regulation, until the general Impact Assessment (initiated under the Vision for Agriculture and Food) has been finalized. Otherwise, it is impossible to reflect the actual impact of such significant amendments – i.e. including weighing the full range of 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:

Recital (27)

(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. On this basis the Commission may, if appropriate, propose amendments to the legal framework, including to Article 14 of Regulation (EC) No 396/2005. 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 **should shall be reconsidered and accordingly** set at the limit of quantification (technical zero), if appropriate based on a prior impact assessment. The decision on setting or lowering MRLs should take into account, in addition to the risk assessment of the Authority, an assessment of the impact on the food and feed chain in the Member States, in compliance with international obligations, in particular the General Agreement on Tariffs and Trade 1994 and the Sanitary and Phytosanitary Measures Agreement.

Article 14 is amended as follows:

- (a) ~~In paragraph (2),~~ a new subparagraph **(2a) is inserted**~~is added~~:
- **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**, according to the latest available evaluation under Regulation (EC) No 1107/2009 or to a specific evaluation in

accordance with Article 43 of ~~this Regulation (EC) No 396/2005~~, a MRL ~~that has been set based on a CXL or a GAP implemented in a third country can be revoked and shall be~~ **reconsidered and accordingly** set in accordance with Article 18(1)(b) or Article 16 if considered appropriate in the light of the ~~outcome of an~~ **of this Regulation based on a prior** impact assessment, **taking into account in addition to the risk assessment of the Authority, an assessment of the impact on the food and feed chain in the Member States, in compliance with international obligations, in particular the General Agreement on Tariffs and Trade 1994 and the Sanitary and Phytosanitary Measures Agreement.**

By derogation from the duration foreseen in Article 14(1), 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 or criteria referred to in the first subparagraph.

This paragraph shall not apply to MRLs for 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.’;

In addition, transitional measures are proposed for products that met the old Maximum Residue Limits (MRLs). As a result, such products, which are already in the distribution chain or have at least been stored with a view to sale on the EU market, may remain on the market for a certain period in order to prevent food waste. The compromise proposal has added that storage may also take place in a third country. When products enter the Union, they must comply with the legislation in force at that time, otherwise it is not enforceable at border controls.

The Netherlands wishes to express its concerns that the current proposal creates inherent risks for the EU and calls upon the European Commission to publish the aforementioned general Impact Assessment as soon as possible, and to use its results to fully revise Regulation (EC) No 396/2005 accordingly.

Regulation 1107/2009

The Netherlands considers it in regards to Regulation 1107/2009 very important that the level of protection for humans, animals and the environment is maintained, but is not yet convinced that this will be the case on the basis of the current compromise text.

The Netherlands therefore wishes to press for the establishment of a European early-warning system to collect scientific literature and monitoring data. By having such a EU vigilance system 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.

The establishment of such early-warning system could be ensured by including the following text (preferably 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 for consideration.

Furthermore, the proposed changes aimed at facilitating the access to the market of products containing only substances which have not been approved before a certain date should be reversed. Instead of facilitating market access, these changes are expected to lead to less efficient assessments for new substances to which the standard assessment methodology applies (i.e., non-biocontrol and non-low risk), as the assessment relevant for each of the zones will still need to be performed and the expertise to do so is limited to member states within each of the zones. This concerns the proposed changes to Article 33(2)(b): authorisation or amendment of authorisation and Article 40(1)(c): mutual recognition).

Regulation 528/2012

Finally, in regards to Regulation 528/2012, the Netherlands is of the opinion that the proposed measures do not provide sufficient safeguards for the protection of human health, animals, and the environment, and may in fact have a negative impact.

A specific concern is that the periodic assessment of substances (at EU level) is extended to every 15 or 25 years, while simultaneously maintaining the periodic assessment of biocidal products at Member State level every 10 years. This increases the workload for national assessing authorities, as they must incorporate the most recent available knowledge, rather than this being done at the substance level by the EU. This also leads to reduced harmonisation within the Union and higher burdens on industry.

Instead, the Netherlands strongly prefers strengthening Article 15 by including a mandate for the European Commission to task the Agency with conducting a periodic review of new scientific literature and monitoring data. This would enable a faster and more effective incorporation of new scientific insights and enhance harmonisation within the Union.

AUSTRIA

ÖSTERREICH

Austrian questions and comments regarding Omnibus X – 10 July 2027

ad Regulation (EC) No 396/2005 (Doc. 11412/26):

explanations of AT positions, outstanding issues and and questions

Article 14 (2a)

- **Why does AT support retaining an explicit appropriateness safeguard in Article 14(2a)?**
 - AT supports retaining an explicit appropriateness safeguard to ensure that an MRL is lowered or newly established only where this is considered appropriate on the basis of the preceding specific impact assessment. This should be done in accordance with recitals (27) and (29a):
... a MRL may be set in accordance with Article 18(1)(b) or Article 16 of this Regulation, where considered appropriate in light of the outcome of a prior impact assessment.
- **Why is it essential from AT's perspective to clarify the interplay between Regulations (EC) No 396/2005 and No 1107/2009?**
 - From AT's perspective, it is essential to clarify the interplay between Regulation (EC) No 396/2005 on maximum residue levels of pesticides and Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.
 - In this context, we would once again like to refer to the outstanding questions (see AT comments following the AGS of 29 May 2026; Doc. 7796/26; see questions below).
- **Why does AT attach particular importance to the presentation of an impact assessment or the inclusion of an evaluation clause?**
 - AT reiterates its call for the presentation of an impact assessment or the inclusion of an evaluation clause.
 - AT attaches particular importance to the presentation of an impact assessment in order to appropriately evaluate the effects of a closer alignment of production standards on consumers, fair conditions of competition, national enforcement, control and monitoring systems, resource requirements, as well as agricultural, environmental and trade policy aspects.
 - **Alternatively**, with regard to Regulation (EC) No 396/2005, AT would welcome a declaration of intent by the European Commission confirming the submission of an impact assessment for publication, the results of which would be examined by the Council and the European Parliament with regard to the appropriateness of further measures, including possible amendments to the legal framework.
- **Questions concerning the new subparagraphs in Article 14(2) of Regulation (EC) No 396/2005:**
 - 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 Regulation (EU) No 528/2012 (Biocides):

From AT’s perspective, the **simplifications to the Biocidal Products Regulation do not go far enough** and do not achieve the objective of simplification. The objective is the **rapid completion of the work programme**. To this end, **AT proposes the following two measures:**

1) AT calls for approval extensions renewals also for active substances that meet the exclusion criteria or that are candidates for substitution.

- These may be granted for shorter periods, in any case for 3, respectively 5 years. They are necessary because the current approval periods of 5 and 7 years are too short. The reason for this is that applications for renewal of active substance approvals must be submitted no later than 550 days before the expiry of the approval.
- If an active substance approval has been granted for 5 years, the renewal application must already be submitted again after 3½ years.
- There is only a short pause between the approval and the renewal application, and the authorities have the active substance back on the table again. However, the authorities need capacity to complete the work programme.
- In most cases, no alternative active substances that would justify the short approval periods are available within 3½ years either.

2) AT calls for an extension of the possibility of derogation under Article 19(5) BPR so that biocidal products can continue to be made available to the general public.

- Due to chemical-law classifications of active substances, biocidal products may currently no longer be made available to the general public by operation of law. Active substances are continuously being classified under chemicals legislation.
- An extension of the possibility of derogation is therefore necessary, at least for those active substances whose chemical-law classification is based solely on oral exposure, since no biocidal product is used orally.
- Without an extension of the derogation, labour-intensive emergency authorisations or special solutions, such as in the case of ethanol, will become necessary.”

POLAND'S COMMENTS ON THE OMNIBUS X SIMPLIFICATION PACKAGE

Article 1

Amendments to Regulation (EC) No 1107/2009

Point 9 (“Article 14 is replaced by the following:”)

PL positively assesses the possibility of establishing a shorter renewal period, as it provides necessary flexibility.

However, PL would like to highlight the following concerns:

- the proposal does not specify the criteria or methodology for determining when a shorter period should be applied and what its duration should be;
- it is unclear which types of concerns or uncertainties should lead to, for example, a 5-, 10-, 15- or 20-year renewal period;
- without clear and consistent criteria, similar cases may be treated differently, creating a risk of unequal treatment and reduced regulatory predictability.

PL therefore considers that clear and transparent criteria should be established to ensure consistent treatment of comparable cases.

Point 21 (“in Article 33, paragraph 2, point (b) is replaced by the following:”)

PL generally supports the proposed concept as a tool to promote new active substances and reduce duplication of assessments.

However, PL would like to highlight the following concerns:

- based on current experience, differences in requirements exist not only between zones, but also between Member States within the same zone;
- this may lead to disputes concerning the quality and completeness of the assessment and whether national conditions have been sufficiently taken into account;
- as a result, the assessment process may become more complex and take longer, which could ultimately delay the placing of a new plant protection product on the market.

Therefore, it is important to ensure an effective mechanism for involving other Member States and addressing differences in national conditions during the assessment.

Point 24 (“Article 40 is replaced by the following:”)

PL generally supports the proposed concept as a tool to promote new active substances, reduce duplication of assessments and facilitate access to new plant protection products.

However, PL would like to highlight the following concerns:

- differences in requirements, agricultural practices and environmental conditions exist not only between zones, but also between Member States within the same zone;
- this may lead to disputes concerning the comparability of conditions and whether the assessment carried out by the reference Member State provides a sufficient basis for mutual recognition in another zone;
- as a result, the procedure may become more complex and take longer, which could delay the placing of a new plant protection product on the market;
- it should also be ensured that cross-zonal mutual recognition is based on an assessment which has genuinely taken into account the conditions of all relevant zones.

PL therefore considers that the proposal should preserve sufficient safeguards to ensure that mutual recognition does not rely on an assessment which is incomplete or not representative of the conditions in the Member State concerned.

Point 33a (“In Article 53, paragraph 1, a third subparagraph is inserted:”)

PL generally supports the proposed direction as a tool to reduce duplication of work and facilitate a rapid response to emergency situations.

However, PL considers the current wording insufficiently precise and would like to highlight the following concerns:

- an emergency authorisation granted by another Member State should not be automatically replicated or treated as a simple mutual recognition of the original authorisation and its conditions;
- the competent authority should verify, in relation to its own territory, whether the emergency situation actually exists, what its scale is, whether other reasonable means of control are available and whether the proposed conditions of use are appropriate;
- the same zone does not necessarily mean the same phytosanitary, agronomic or regulatory conditions;
- it should be clarified who may apply for such an authorisation in the second Member State and what information or documentation should be submitted;
- the meaning of “the same emergency authorisation” should also be clarified, in particular whether the second Member State may adapt the conditions of use and risk mitigation measures to its national circumstances.

PL therefore considers that the proposal should clearly preserve the responsibility of each Member State to verify that the conditions of Article 53(1) are fulfilled on its own territory.

Amendment to Regulation (EU) 2017/625

Point 2

Poland maintains its proposal to amend Article 50(3) of the OCR by explicitly providing for the possibility of splitting consignments subject to official controls under Article 44 of the OCR. This amendment would eliminate legal uncertainty regarding the application of the OCR provisions and ensure equal treatment of consignments regardless of the legal basis for their official controls. If, in the PREZ assessment, such consignments may already be split without amending the legislation, we kindly request that this clarification be included in the recitals.

Rationale:

The proposed Article 50(3) of the OCR provides that the possibility of splitting consignments applies to goods referred to in Article 47(1) of that Regulation, i.e. goods regulated under Articles 72 and 74 of Regulation (EU) 2016/2031. However, it does not provide for the possibility of splitting consignments of goods regulated under Article 73 of Regulation (EU) 2016/2031, which are subject to official controls pursuant to Article 44 of the OCR.

Poland is of the view that the possibility of splitting consignments should also apply to goods regulated under Article 73 of Regulation (EU) 2016/2031.

The explicit provision in the OCR stating that consignments subject to official controls under Article 47(1) of the OCR may be split leads to the interpretation that consignments controlled under other provisions (i.e. Article 44 of the OCR), as well as consignments containing both goods controlled under Article 47(1) and goods controlled under Article 44 of the OCR, may not be split.

The amendment proposed by Poland is intended to avoid legal uncertainty, ensure legal clarity, and promote the uniform interpretation and application of the relevant provisions by Member States and economic operators.

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 finalised 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.’

Article 12

Entry into force and application

Point (a):

Poland opposes the deletion of point (a), which provides that the amendments to Regulation (EC) No 1107/2009 should apply 12 months after the date of entry into force of the Regulation.

In Poland's view, the changes to the procedures for the placing on the market of plant protection products introduced by the proposed regulation are so far-reaching that they require amendments to national legislation governing the relevant administrative procedures. It is therefore necessary to provide for an appropriate transitional period. Otherwise, these changes would lead to legal uncertainty regarding the applicable procedures.

PORTUGAL

PORTUGAL

- 1) On article 4, we consider that the proposed addition is only relevant in paragraph 3, as risk mitigation measures, by definition, relate exclusively to the use of plant protection products. It is therefore not appropriate to refer to them in the context of compliance with the cut-off criteria laid down in points 2 and 3 of Annex II to the Regulation. We therefore suggest the following amendment to Article 4(1):

*«4.1. An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge **including risk management measures and application techniques**, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3.»*

- 2) We would like to recall our drafting suggestion for Article 46 (Grace period), which would provide Member States with greater flexibility where the withdrawal is based on reasons other than safety considerations:

*«2. Where a Member State withdraws or amends an authorisation or does not renew it for other reasons than those referred to in paragraph 1, it may set a grace period that shall **normally** not exceed 6 months for the sale and the distribution and an additional maximum of 1 year for the disposal, storage, and use of existing stocks of the plant protection products concerned).»*

- 3) We maintain a scrutiny reservation on the amendments proposed to Article 33. We do not fully understand the purpose of the proposed amendments, their intended scope or their practical implications. We would therefore appreciate further clarification, in particular regarding the rationale for these changes.
- 4) We also maintain a scrutiny reservation on the amendments proposed to Article 53. At this stage, we have reservations as to their added value compared with the current Regulation and would welcome further clarification on the rationale for these changes.

ROMANIA

ROMÂNIA

Reiteration in relation to the Irish Presidency proposal entering into negotiation on 9 July 2026 (WK 9779/2026 INIT, ST 11412/26) and comparatively analysing the Cypriot Presidency text 10004/26 and 10004/26 COR 1.

With a view to the meeting of the Antici Group on Simplification (AGS) on 9 July 2026, Romania hereby reiterates the technical position previously transmitted within the working groups, in relation to the compromise text presented by the Irish Presidency on 3 July 2026 (WK 9779/2026 INIT and ST 11412/26).

The analysis shows that none of Romania's technical requests have been integrated into the Presidency compromise text. Romania calls on the delegations and the Presidency to re-examine these proposals before the finalisation of the negotiating mandate with the European Parliament.

Article	IE Presidency proposal (9 July 2026)	Romania's position (reiterated)	Justification
Article 4(7) – the notion of 'serious danger to plant production'	The Presidency text of 3 July 2026 (ST 11412/26, Article 1(3)(c)) leaves the wording of Article 4(7) unchanged: an active substance may be approved for a maximum of five years where necessary to control a serious danger to plant health or plant production that cannot be contained by other reasonable means. The Presidency's changes to Article 4 are limited to paragraphs (1) and (3) (reference to innovative application techniques); paragraph (7) is not amended.	Romania reiterates its proposal to supplement Article 4(7) by clarifying that the notion of 'serious danger to plant production' includes recurrent and structural damage caused by endemic soil pests in specific biogeographical regions of the Union, where pest densities systematically exceed the Economic Damage Threshold and no effective alternative plant protection methods are available, as demonstrated by multi-annual phytosanitary monitoring data.	The absence of an explicit legal definition of 'serious danger' maintains the legal vulnerability of the repeated authorisations granted under Article 53 in 2019-2024 to control the soil pest <i>Tanymecus dilaticollis</i> , specific to the steppe region present exclusively on Romanian territory within the Union. The proposal does not alter the approval thresholds or criteria; it clarifies a notion already present in the Regulation.
New Article 4(8) – risk-benefit balancing mechanism	The 3 July 2026 compromise text does not introduce a new Article 4(8) and contains no comparative risk-benefit assessment mechanism at the level of approval or renewal of active substances. The discussion rounds proposed by the Presidency for the AGS meeting	Romania reiterates its proposal for a new Article 4(8), under which an active substance may be approved or its approval renewed where non-approval would have a disproportionate negative impact on agricultural viability, food production or food security compared to	The principle of proportionality (Article 5 TEU), read together with the food security objectives of Article 39 TFEU, requires assessment of the disproportionate impact of non-approval or non-renewal decisions. The mechanism is distinct from the Article 4(7) derogation,

Article	IE Presidency proposal (9 July 2026)	Romania's position (reiterated)	Justification
	(renewal, reassessment, EFSA mandate) do not address this point.	the risks to human health, animal health or the environment, provided that appropriate risk mitigation measures are applied.	as it applies to renewal or review procedures rather than situations of immediate danger.
Article 11(1a) – coordination of the rapporteur Member State with unique biogeographical regions	The wording of Article 11(1a) in the 3 July 2026 text remains the one agreed under the previous Presidency: the rapporteur Member State gives priority to the assessment of applications for biocontrol substances. No obligation to coordinate with Member States whose territory includes biogeographical regions not represented in standard test conditions has been introduced.	Romania reiterates its proposal to supplement Article 11(1a) so that, where the intended use of an active substance concerns biogeographical regions with pedoclimatic conditions not represented in the rapporteur Member State's test conditions, that Member State is required to coordinate with the Member States whose territory includes those regions.	Romania hosts five of the Union's eleven biogeographical regions, including the steppe region, present exclusively on national territory. National research institutes (INCDPP, INCDA Fundulea, the ASAS research stations) hold monitoring data for these regions that are not currently formally used in the Union authorisation procedure.
Article 29(3) – mandatory testing in regions with specific pedoclimatic conditions	Article 29(3) is not among the articles amended by the 3 July 2026 compromise text. The current requirement for tests 'representative of the predominant conditions in the area of use' remains unchanged.	Romania reiterates its proposal to supplement Article 29(3) so that, where the intended area of use includes biogeographical regions with specific pedoclimatic conditions not represented in the tests conducted by the rapporteur Member State, supplementary efficacy and risk data collected under the conditions of those regions are required, and taken into account both in the authorisation decision and in the mutual recognition procedure under Article 40.	Annex I, read together with Article 3(17), places Romania and Germany in the same Zone B, although pedoclimatic conditions are fundamentally different. Where the alternative proposed for a withdrawn substance has not been tested under the conditions of the replacement region, the scientific basis for substitution remains incomplete.
Article 49 – treated seeds; qualification of sowing as a 'use'	Article 49(1) of the 3 July 2026 compromise text keeps the wording under which the treatment of seeds, as well as the sowing of treated seeds, 'constitutes a use of a plant protection product' - a position Romania opposed at the AGRIFISH meeting of February 2026. The 9 July 2026 text does not introduce the paragraphs (3)(a) and	Romania reiterates its position that the treatment of seeds and the sowing of treated seeds do not constitute a use of a plant protection product, together with its proposal for a new paragraph (3)(a) allowing Member States not to prohibit treated seeds placed on the market under a derogation granted pursuant to Article 2 of the	Amending the implementing regulations is a necessary legal consequence of introducing Article 49(3)(a), under the principle of effet utile. The Court of Justice ruling in Case C-162/21 (Pesticide Action Network, 19 January 2023) excluded reliance on Article 53 for substances whose use is restricted by Union-level acts,

Article	IE Presidency proposal (9 July 2026)	Romania's position (reiterated)	Justification
	(3)(b) proposed by Romania and does not provide for any amendment to Implementing Regulations (EU) 2018/783, 2018/784 and 2018/785.	implementing regulations, where that derogation is based on a documented and systematic exceedance of the Economic Damage Threshold for endemic soil pests in officially delimited areas. Romania also reiterates its proposal for a new paragraph (3)(b) amending Implementing Regulations (EU) 2018/783, 2018/784 and 2018/785 accordingly.	which makes an alternative structural legal route necessary.
Article 53 – emergency authorisations for seed treatment	In the 3 July 2026 text (ST 11412/26, point 33a), the Presidency introduced a new third subparagraph to Article 53(1), under which another Member State from the same zone may grant the same emergency authorisation on the basis of the detailed information transmitted. This amendment addresses mutual recognition of emergency authorisations between Member States of the same zone and does not address the specific legal issue raised by Romania in relation to seed treatment following Case C-162/21.	Romania reiterates its proposal for a new Article 53(1a), allowing Member States to grant emergency authorisations for seed treatment uses of active substances covered by Implementing Regulations (EU) 2018/783, 2018/784 and 2018/785, where officially delimited areas show a documented systematic exceedance of the Economic Damage Threshold, no effective alternatives are available, and the use is strictly limited to seed treatment.	The new mutual-recognition provision introduced by the Presidency resolves a distinct administrative issue but does not remove the legal vulnerability created by Case C-162/21 for the emergency authorisations granted by Romania in 2019-2024 for seed treatment. The paragraph proposed by Romania is complementary to Article 49(3)(a)-(b): it provides a temporary emergency route, limited to 120 days, pending implementation of the structural mechanism.

SLOVENIA

SLOVENIJA

Slovenia would like to thank the Presidency for its intensive work and for preparing a compromise text. However, Slovenia still has concerns about two issues:

First, on MRLs, the current compromise text still allows MRLs above the limit of quantification (LOQ) for active substances that are not approved in the EU. We believe that this approach does not provide a sufficient level of consumer protection and does not create equal conditions for EU farmers.

Second, regarding genetically modified microorganisms (GMMs), Slovenia considers that the proposed provisions are not sufficiently clear and precise. In particular, the requirements for the removal of GMMs are not defined clearly enough, which could create difficulties for implementation and enforcement. The key criteria should be set out in the Regulation itself.

In addition, Slovenia would like to provide the following written comments in response to the Presidency's questions discussed during yesterday's meeting.

FIRST ROUND – Balance between simplification and safeguards

- Slovenia considers that the proposed changes do achieve a satisfactory balance.
- Risk-management clarifications (Art. 4) do not lower safety standards.
- Shorter renewal periods in case of uncertainties (Art. 14) fit our precautionary approach.
- Targeted reassessment (Art. 18a) ensures rapid integration of new scientific evidence.
- Allowing the Commission to mandate EFSA reviews (Art. 21) strengthens scientific consistency.
- Removal of delayed application is acceptable.

SECOND ROUND – Sufficiency of simplification

- Slovenia considers the second-round measures to bring sufficient simplification.
- The one-zone approach for low-risk substances is acceptable with **pedoclimatic considerations**.
- Mutual recognition for newly approved substances is useful if products are **actually on the market** in the reference MS.
- Slovenia strongly supports the **removal of tacit agreement**.
- Emergency derogations must remain **strictly limited to genuine emergencies**.

- Concerning recitals we have **comment on recital 4** - we propose to add wording "**provided they are not candidates for substitution**" to the amended text, just as stated in Articles 33 and 40 and in accordance with recital 10.
- **One-zone approach for low-risk active substances** (Article 33(2)(b)) – SK supports the proposed approach, but **we see the inconsistency with recital 10** and we propose to replace words "**active substances not yet approved in the Union**" with "**that have not been approved in the Union at**", as stated in Article 40 for mutual recognition.
- **Mutual recognition** based on a one-zone approach for newly approved substances (Article 40(1)(c)) – SK supports the proposed approach, but **we see the inconsistency with the zonal approach**. If a one-zone approach for low risk active substances is introduced for a zonal application, we propose that this should also be applied for mutual recognition.
- **Abolition of tacit consent** (Article 37(5) and 42(3); recital 10 and 10a) – SK fully supports deletion of tacit agreement.
- **Emergency authorisations** - exemptions for 120 days (Article 53(1)) – we support the positive changes in Article 53, however, it's not enough and we have doubts that the change proposed by the Presidency will bring the desired simplification and benefit to plant protection practice. We propose a technical discussion on this article and recall that we have already submitted a proposal for amendment to Article 53, which was supported by some other Member States.

Proposal for change of Article 53:

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,
 1. the placing on the market and use of plant protection products, not authorised in a member state,
 2. the use of authorised plant protection product beyond the scope of existing authorisation,
 3. 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.

- **Article 59 and data protection** - SK request following change of the Art.59 para 6:

6. The period of data protection shall be **13 years** starting from the date of the authorisation in the first Member State granting an authorisation based on a dossier including the test or study report. That period is extended to **15 years** for plant protection products covered by Article 47.

FINLAND

SUOMI

- Finland wants to thank the Presidency for their hard work with the compromise text.
- Finland can support the compromise text. However, we would like to note that the text does not provide the best possible basis for the trilogues, particularly regarding the approval periods for active substances of plant protection products and the stringency of the maximum residue limits. We would also like to express our support for the valuable amendment proposals put forward by Germany.

SWEDEN

SVERIGE

Please find below comments from Sweden following the Antici meeting 9 July on Regulation (EC) 1107/2009, as part of Omnibus X on Food and Feed Safety

(text proposals indicated in **bold underlined**)

Article 4.1 and 4.3

Sweden considers the proposed clarification to be justified. However, we suggest adding the word “realistic” in Article 4.1, as is already the case in Article 4.3. We also consider that it should be clarified that the term “technical knowledge” is the element intended to be further specified.

- ‘1. An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, **including which includes realistic risk management measures and application techniques**, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3.’
- (b) the chapeau of paragraph 3 is replaced by the following:
- ‘3. A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, **including risk management measures and application techniques**, shall meet the following requirements:’

Article 4.7

Sweden considers that the combined effect of the proposed amendments to Article 4(7) would lower the level of protection for human health and the environment and could reduce the incentive for companies to develop new, less hazardous active substances or non-chemical alternatives. In addition, allowing applications under Article 4.7 to be submitted ‘during the approval process, creates an obvious risk of delaying decision making.

Furthermore, the proposed amendment to Article 4.7 would broaden its scope to include not only substances that fall for the so called 'cut-off criteria', but also substances for which unacceptable risks have been identified. We therefore suggest adding text clarifying that the impacts on human health and the environment arising from uses authorised under this provision should be considered and reflected in the decision (**see proposed wording in bold and underlined below**).

In addition, Sweden suggests that endocrine disruptors for which no threshold can be established should be added to the list of substances that cannot be considered for approval under article 4.7, in line with carcinogenic substances classified as category 1B without a threshold.

- ‘7. 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, information provided in the course of the approval 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, 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.

Before granting such approval, the Commission shall consider the foreseeable consequences of the proposed uses for human health, and the environment, taking into account the proposed conditions of use and risk mitigation measures.

An approval under this paragraph may only be granted where the serious danger to plant health or plant production outweighs the identified adverse consequences for human health and the environment.

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 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~~ **may** draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods, ~~and shall without delay transmit that plan to the Commission.~~

Article 14

Sweden welcomes the intention to clarify that shorter approval periods may be appropriate where uncertainties remain in the risk assessment. Furthermore, as previously stated, Sweden supports the principle of time-limited approvals and regular reviews of active substance approvals. However, Sweden considers that an approval period of 25 years is too long and therefore **proposes retaining the current maximum period of 15 years for renewed approvals.**

Article 18(a)

Sweden would like to stress that where the Commission decides not to include a substance in a work programme pursuant to Article 18a, despite such inclusion having been requested by EFSA or by a Member State, it should provide a reasoned and publicly available explanation. This will be important for ensuring transparency, maintaining public trust and the credibility of the system. T

The following addition is therefore proposed:

“Where the Commission decides not to include a substance in a work programme where such inclusion has been requested by the Authority or by a Member State, it shall provide a reasoned and publicly available justification.”

Article 27(a)

Sweden supports the proposal to exclude certain substances, in particular those of highest concern, from extended approval periods. Sweden particularly welcomes the inclusion of point (c). Sweden also welcomes the Presidency’s efforts to take account of substances undergoing review under Article 21. However, we suggest moving point (d) from paragraph 2b to paragraph 2a.

The purpose is to ensure that active substances of highest concern which meet the criteria set out in points (a), (b), (c) or (e) of the new paragraph 2b are not granted extended approval periods solely because they are undergoing a review under Article 21. Instead, such substances should be treated in the same manner as other active substances of comparable concern.

The following amendment is therefore proposed:

2a” For active substances not covered by paragraph 1 which are approved on [OP: please insert the date] and for which no renewal procedure, **or review according to Article 21**, is ongoing on that date [...]

Article 33(2)(b)

Sweden can sympathise with the intention of facilitating faster market access for new active substances but sees significant challenges regarding the practical implementation of the proposal. Furthermore, the proposal to establish a dedicated zone for new substances undermines the principle underlying the EU zonal system, namely that specific environmental and agricultural conditions must be considered, as these factors influence the risk assessment. It is positive that candidates for substitution are excluded from the scope of the proposal. However, the proposal would also apply to new substances that may subsequently prove to have problematic environmental properties.

Article 40(1) (c)

The Presidency's intended objective with the proposed wording on mutual recognition of product authorisations is not sufficiently clear in the text. In its current form, Sweden has difficulties supporting the proposal. We would prefer to retain the previous proposal, under which plant protection products containing only low-risk substances would continue to fall within the scope of this Article.

We therefore propose the following wording:

- (c) the authorisation was granted by a Member State for use in greenhouses, as post-harvest treatment, for treatment of empty rooms or containers used for storing plant or plant products, for seed treatment, for uses that are solely and explicitly needed in order to apply the provisions of Regulation (EU) 2016/2031 ~~or~~, for plant protection products containing as active substances only ~~biocontrol~~ **low-risk** active substances

~~that have not been approved in the Union at [OP: please insert the date of entry into force of this Regulation], provided that they are not candidates for substitution~~ regardless of the zone to which the reference Member State belongs and the authorised plant protection product is placed on the market in the reference Member State.

Article 46

Article 46 should explicitly include a provision, in line with Article 20.2, stating that no grace period may be granted where there are immediate or serious concerns for health or the environment. The following addition to article 46 is therefore proposed:

“In case of immediate or serious concerns for human health or animal health or the environment that led to a withdrawal or non -renewal of the authorisation, the Member States may not set a grace period.”

Joint wording proposal by Estonia, the Czech Republic, Italy, Latvia and Lithuania regarding amendments to Regulation (EC) No 1107/2009 (Articles 4 and 29)

The delegations of Estonia, the Czech Republic, Italy, Latvia and Lithuania propose the following amendments to Articles 4 and 29 of Regulation (EC) No 1107/2009.

In Article 4, paragraph 1, the following indent is added at the end: “An active substance shall be approved if not approving the active substance would have a disproportionate negative impact on the viability of agriculture compared to the risks to human health, animal health, or the environment arising from the use of the substance.”

New amendment to Article 29: In Article 29 paragraph 7 is added:

“(7) Where refusal or withdrawal of an authorisation of a plant protection product in favour of an alternative plant protection product or a non-chemical control or prevention method is considered, annex IV paragraph 3 shall apply.”

Justification:

We consider that, in the absence of effective alternatives to plant protection products, the impact on the viability of crop production — including effects on yields — should also be taken into account when granting authorisations for plant protection products, in order to ensure the availability of plant protection products that are essential for farmers. Unfortunately, no corresponding simplification proposals are included in the draft. Therefore, we consider it necessary to amend the Regulation so that, both when granting approval for active substances and when granting plant protection product authorisations and their mutual recognition, account is also taken of the existence or lack of alternative solutions and of the impact of the relevant active substance—or its absence—on the viability of agricultural production. In principle, this is not a new criterion, as similar aspects are taken into account in the assessment of applications for authorisations for plant protection products containing candidates for substitution. Specifically, under the current rules, when a comparative assessment of a product containing a candidate for substitution considers refusing an authorisation or withdrawing it, the significantly more adverse practical or economic consequences of such a decision must be taken

into account, as described in point 3 of Annex IV to Regulation (EC) No 1107/2009. For example, the disappearance of systemic insecticides from the market has in recent years caused significant economic losses for Estonia's oilseed rape sector. At the same time, all existing criteria for assessing impacts on human and animal health and on the environment would remain unchanged.
