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NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	8691/26
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 852/2004, (EC) No 853/2004, (EC) No 396/2005, (EC) No 1099/2009, (EC) No 1107/2009, (EU) No 528/2012, (EU) 2017/625 as regards the simplification and strengthening of food and feed safety requirements - Presidency compromise text

Delegations will find in the Annex the third Presidency compromise text in relation to the above proposal, limited to provisions relating to Regulation (EC) No 1107/2009.

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

ANNEX

2025/0410 (COD)

Draft

PUBLIC

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

(1) In its Communication A Vision for Agriculture and Food[1], the European Commission announced a cross-cutting simplification package aimed at reducing unnecessary regulatory burdens while maintaining high standards for food and feed safety, human and animal health, and environmental protection.

(2) Ten legal acts in the area of food and feed safety are amended by this Food and Feed Simplification Regulation in order to address certain requirements and procedures which are particularly burdensome for the industry and the competent authorities of the Member States. The targeted amendments aim at rendering the food and feed legislation more efficient and cost-effective for the industry, reduce burdens on the industry and authorities, while at the same time ensuring a high level of protection of human and animal health and of the environment.

(3) Regulation (EC) No 1107/2009[2] sets out the regulatory procedure for approval of active substances and authorisation of plant protection products in the Union.

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1 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Vision for Agriculture and Food Shaping together an attractive farming and agri-food sector for future generations, COM/2025/75, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0075

2 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and

(4) In order to decrease farmers' dependency on plant protection products containing chemical active substances and in line with the announcements in the Communication A Vision for Agriculture and Food, the accessibility and availability of sustainable plant protection products, including plant protection products containing biocontrol substances, needs to increase.

(5) In order to facilitate faster market access for biocontrol substances and products containing them, biocontrol substances need to be more clearly defined and identified under Regulation (EC) No 1107/2009. A definition for biocontrol substances should include: 1) micro-organisms, 2) inorganic substances as occurring in nature, with the exception of heavy metals and their salts, 3) **substances of biological origin or produced synthetically that are functionally and structurally identical,** or 4) substances of biological origin or produced synthetically that are functionally identical and structurally similar to them such as semiochemicals, biological macromolecules or molecules comprised of components thereof, as well as substances, including of unknown and variable composition, originating from living organisms or derived by biological processes (e.g. extracts from plant products, metabolites produced by micro-organisms) and meet the low-risk criteria set out in Annex II point 5 of this Regulation. **In order to benefit from the advantages during product authorisation, the biocontrol substances contained in plant protection products should meet the low-risk criteria set out in Annex II point 5 of this Regulation.**

(6) As many biocontrol substances may also have plant growth stimulation functions, a clearer borderline should be set with regard to fertilising products, in particular plant biostiumlants as referred to in Regulation (EU) No 2019/1009 on the making available on the market of EU fertilising products[3]. Thus, the scope of Regulation (EC) No 1107/2009 should be clarified to include only substances regulating the life processes of plants ~~which~~, such as phytohormones ~~and/~~or other substances that mimic, inhibit, or otherwise modulate endogenous hormonal signalling pathways, thereby producing specific, predictable, and dose dependent

repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, pp. 1–50, http://data.europa.eu/eli/reg/2009/1107/oj)

[3] Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003, PE/76/2018/REV/1, OJ L 170, 25.6.2019, pp. 1–114, ELI: http://data.europa.eu/eli/reg/2019/1009/oj.

physiological or developmental responses influencing plant or plant organs' growth and/or development. Substances stimulating life processes of crops whose effect in the plant are ~~not~~ directly related to better nutrition intake or a nutritional function should remain outside the scope of Regulation (EC) No 1107/2009.

(7) For the same purpose, the evaluation of applications for approval of such active substances and for the authorisation of plant protection products containing them should be given priority to ensure timely crop protection from existing pests and diseases.

(8) The risk assessment of biocontrol substances requires specific technical knowledge, and some Member States do not have enough experts specialised in this type of assessment. As a result, some applicants for approval of biocontrol substances face difficulties in finding a rapporteur Member State. In order to increase capacity for the assessment of new biocontrol substances, it should be possible for the European Food Safety Authority ("the Authority") to assume the role of the rapporteur Member State for the assessment of applications for approval and the Authority's resources should be increased accordingly. The Authority should put in place appropriate safeguards to ensure independence of the subsequent peer review and to avoid any possible conflict of interests for the experts involved at the different stages of the assessment.

(8a) **To facilitate the uniform application of these measures, t**he Commission should mandate the Authority to develop a guidance document clarifying the concept of 'functional identicality and structural similarity' applying to the substances fulfilling the definition of biocontrol substances.

(9) To accelerate the accessibility and availability to farmers of plant protection products containing new **low risk** ~~biocontrol substances~~, Member States should have the possibility to grant provisional authorisations for such products as soon as the Authority has launched the public consultation on the draft assessment report delivered by the rapporteur Member State for an application for approval concluding that the substance can be approved **meeting the criteria set out in Annex II point 5 of this Regulation**. When the new **low-risk** ~~biocontrol~~ substance is approved, and in order to avoid unnecessary administrative procedures, it should be possible to transform such provisional authorisations into regular authorisations without the need of reassessment unless the conditions set out in the approval require an amendment of the conditions set out in the provisional authorisations.

PUBLIC

(10) To reduce burdens on applicants and Member States and to facilitate the availability of plant protection products containing only ~~biocontrol substances or~~ low-risk active substances, the Union should be considered as one zone for applications for the authorisation of such products. ~~Considering also that plant protection products containing only biocontrol substances are not expected to pose different levels of risk in different Member States, mutual recognition of authorisations for such products granted by one Member States should be considered as granted by tacit agreement if decisions on applications for mutual recognition are not adopted within the prescribed deadline.~~

(10a) Where mutual recognition is sought for a plant protection product containing ~~solely~~ ~~biocontrol or~~ **only** low-risk active substances, considering that they are not expected to pose different level of risk in different Member States neither to require risk mitigation measures, and that an assessment was already made by another Member State, such recognition should be deemed granted by tacit agreement if no decision is adopted within the applicable period, **provided that tacit agreement is not contrary to the national law of the Member State concerned. To facilitate the application of this provision, Member States should notify the Commission within strict deadline if their national law does not recognise the tacit agreement**. ~~Where needed, Member States should be able to require additional information from the applicants by setting a period no texceeding 6 months to provide it.~~

(11) […]

(12) Article 22 of Regulation (EC) No 1107/2009 sets out criteria to identify low-risk active substances, referring to hazard-based criteria for the substance set out in point 5 of Annex II to that Regulation and risk-based criteria for the plant protection products containing them set out in its Article 47. Implementation of these provisions has proven difficult in practice as, at the time of the approval or renewal of approval of active substances, it is generally not known whether the criteria related to products in Article 47 can be fulfilled or not. The approval criteria for low-risk substances should therefore be limited to the intrinsic properties of the active substance. Furthermore, there have been cases where an active substance could not be approved as low-risk because certain elements related to the criteria could not be fully clarified during the approval or renewal of approval procedure, while further information generated later showed that these are fulfilled. To address such situation, he possibility to apply for a change of the status of an approved active substance to low-risk should be introduced.

PUBLIC

(13) The provisions related to basic substances in Regulation (EC) No 1107/2009 have proven to be unclear, which has led to disharmonised implementation across Member States and hinders the availability of those substances to farmers. Therefore, a clear definition of basic substance should be included in Article 3. specifying that basic substances include foodstuff as defined under Article 2 of Regulation (EC) No 178/2002 as well as substances for which any relevant evaluations, carried out in accordance with other Union legislation regulating the use of that substance for purposes other than for a plant protection product, show that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment.

(14) Separate provisions for the approval criteria for basic substances and the application procedure should be set out, as well as more specific labelling requirements to better inform users about the conditions of use. It should also be clarified that in addition to use, the placing on the market of approved basic substances for plant protection purposes does not require an authorisation by Member States to allow for easier access to basic substances by farmers in a suitable form. Transitional provisions should be added so that all basic substances that are approved at the moment of the entry into force of this Regulation could be placed on the market in the Union, without any restrictions stemming from the superseded rules, ensuring level-playing field for all users in all Member States.

(14a) In order to support a transition towards more sustainable active substances and plant protection products, resources in the Member States currently dedicated to renewal procedures should be made available for the assessment of applications for new active substances and products. Therefore, approvals for **low-risk** active substances and authorisations for plant protection products containing ~~those~~ **only low-risk** active substances should become unlimited in time, ~~except for active substances that are candidates for substitution, those approved under Article 4(7) of Regulation (EC) No 1107/2009 as these have properties that are of concern to human or animal health or the environment and those approved for a limited period for reasons linked to the results of the risk assessment. It should still be possible to set time limits for approvals if found appropriate in the light of the outcome of the risk assessment conducted prior to a decision on an approval. The Commission should also be able to identify active substances with unlimited approval for which a full renewal procedure should be carried out or identify active substances with unlimited or limited approval periods for targeted reassessment. Identification of active substances should be based on multiple criteria and requests from~~

~~Member States.~~ In addition, the possibility for ad-hoc reviews of active substances at any time as already foreseen in Article 21 of Regulation (EC) No 1107/2009 should be maintained.

(15) In the interest of predictability, efficiency, consistency and transparency, rules setting out the provisions necessary for the implementation of targeted reassessments should also be created to verify if existing criteria are still met or if new criteria are fulfilled. Targeted reassessments should be conducted through a dedicated work programme. This work programme should be communicated transparently with clear planning and timelines, so that competent authorities of Member States can plan accordingly. ~~Furthermore, the Commission should mandate the Authority to periodically perform a literature review to advise on the planning of the work programme. The output resulting from this mandate would support prioritising reassessments and planning of the work programme.~~

(15a) Following the targeted reassessment of an active substance, safener or synergist, existing plant protection products containing those substances should also be reassessed to check whether they comply with the conditions of approval for the active substance, safener or synergist contained therein, and with the requirements for authorisation of plant protection products set out in Article 29 of Regulation (EC) No 1107/2009. Applicants should provide the necessary information to demonstrate such compliance and Member States should assess it.

(16) Article 4(7) of Regulation (EC) No 1107/2009 provides for a derogation to allow for the approval of active substances not meeting the approval criteria laid down in Article 4 and Annex II where it is necessary to do so because of a serious danger to plant health or plant production which cannot be contained by other reasonable alternatives including chemical and non-chemical methods with comparable costs, availability and efficacy, except for active substances having particularly hazardous properties. Experience has shown that it is necessary to clarify the scope of the criteria for which such derogation is possible. A harmonised derogation in certain cases where a serious danger to plant health which cannot be contained by other reasonable means would reduce the administrative burden for Member States authorising plant protection products containing such active substances under Article 53 and will contribute to reducing disparity for access to plant protection products containing the substances concerned between the farmers located in different Member States. It should also be possible that in addition to the information included in an application for approval or renewal of approval of an active substance any other information provided in the course of

the approval procedure may also be taken into account when considering the possibility to grant the derogation.

(17) In order to support Member States lacking sufficient technical or scientific expertise to complete their tasks as rapporteur Member States within the periods foreseen in Regulation (EC) No 1107/2009, it should be possible for rapporteur Member States to ask the Authority for support when preparing the draft assessment report for an application for approval or renewal of approval, assessing additional information required during an evaluation and updating the draft assessment report after its initial submission. The Authority should put in place appropriate safeguards to ensure independence of the subsequent peer review and to avoid any possible conflict of interests for the experts involved at the different stages of the assessment.

(18) Following the non-renewal of approval of an active substance, Member States are to withdraw all authorisations of plant protection products containing that active substance and farmers are to stop using those products. In such situations, Member States need time to enact withdrawals of product authorisations and existing stocks of products become waste unless grace periods are foreseen to allow for placing on the market and use of such stocks. In addition, farmers need time to find alternatives for the no-longer authorised products. Article 20 of Regulation (EC) No 1107/2009 provides the possibility in certain cases the Commission to set maximum grace periods for placing on the market and use of existing stocks of plant protection products for which authorisations are to be withdrawn. However, the conditions set in Article 20 for when such maximum grace periods can be granted should be amended to clarify that the setting of a maximum grace period for distribution and use of existing stocks of plant protection products for which authorisations have to be withdrawn is possible in general, except for cases where there are immediate and serious concerns for human or animal health or the environment and to clarify the link with Article 46. Additionally, the time limit for grace periods of 18 months is insufficient in cases where there are no alternative plant protection products available on the market in particular Member State at the time of withdrawal of the authorisations. Therefore, the maximum duration of grace periods that Member States may set should be increased to a total period of 3 years in such cases so that it allows the Member States enough time to have alternative plant protection products authorised and to allow the farmers to adapt their crop protection solutions. For the same reasons, the grace periods in which the Member States may grant under Article 46 following withdrawals or amendments of authorisations should be aligned with the maximum possible under Article 20.

PUBLIC

(19) The requirement for Member States to consider current scientific and technical knowledge relevant for the active substance in the context of product authorisations has led to some confusion and divergent interpretation among Member State, diverging outcomes of risk assessments, and, as a consequence, unequal access to plant protection products for farmers depending on the Member State of their establishment. It is therefore necessary to clarify that the Member States should normally rely on in the latest active substance assessments at Union level, while also acknowledging that updates may be needed and in such cases the Member States should notify the Commission so that the scientific and technical knowledge is assessed in a harmonised way.

(20) Regulation (EU) 2016/2031[4] aims at preventing the establishment or spreading of pests that would have unacceptable economic, environmental or social impacts on the Union territory including impacts on agricultural production. The timely availability of authorised plant protection product uses is essential to apply the provisions of this Regulation. Member States have repeatedly mentioned difficulties in this regard and, therefore, the timely availability of authorised plant protection product uses across all Member States to prevent the entry into, and spread within, the Union, of pests listed in accordance with Articles 5(2), 30(1), 32(3), 37(2) of Regulation (EU) 2016/2031 should be facilitated.

(21) In order to prevent abuse of the mutual recognition system in the light of divergent fees set by the Member States for obtaining authorisations for plant protection products, applications for mutual recognition of a product authorisation should only be possible if the product for which authorisation by mutual recognition is sought is actually placed on the market in the reference Member State. Furthermore, in cases where companies decide to only apply for authorisation of a plant protection product in certain Member States but not in others, it should be made easier for official or scientific bodies involved in agricultural activities or professional agricultural organisations to apply for mutual recognition of product authorisations in these other Member States by lifting the obligation to obtain the consent of the authorisation holder.

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4 Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, pp. 4–104, ELI: http://data.europa.eu/eli/reg/2016/2031/oj).

Moreover, the administrative burden for such applicants, as well as for applicants for the extension of authorisations of products for minor uses, should be reduced by removing the obligation to provide, as part of the applications, certain documents which can be obtained directly from the reference Member State having granted the authorisation for which mutual recognition or extension is sought.

(22) ~~Divergent views among Member States on whether the sowing of treated seeds constitutes a use of plant protection products has created confusion amongst producers of treated seeds, farmers and competent authorities. Additionally,~~ **T**There are different interpretations as to whether the provision on treated seeds cover also other types of plant reproductive materials such as tubers, bulbs, or seed potatoes. The lack of clarity creates barriers for the free circulation of treated ~~seeds and~~ plant reproductive materials and at the same time has created disparity between the Member States as regards imports of seeds treated with active substances not approved for use in the Union ~~and their sowing~~. Therefore, the relevant provisions should be clarified, in order to increase harmonisation among Member States **by extending the current rules to plant reproductive materials other than seeds and clarifying the conditions under which such products could be placed on the Union market.** ~~. The measures would not create additional burden for the seed treatment industry as treated seeds themselves are still not to be considered a plant protection product. The administrative burden for the farmers should be limited thus specific derogation for the machinery used for the sowing of treated seeds should be provided so that it is not to be regarded as pesticides application equipment within the meaning of Directive 2009/128/EC[5] on the sustainable use of pesticides.~~

(23) Some of the conditions for obtaining authorisations for plant protection products for minor uses set out in Article 51 of Regulation (EC) No 1107/2009 haven proven to be too restrictive and should be removed in order to make more products available to farmers. Furthermore, the implementation of that Article varies significantly across Member States. Therefore, the transparency should be improved, and the Commission should be empowered to adopt implementing acts harmonising the procedures for granting extensions of authorisations for

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5 Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, (OJ L 309, 24.11.2009, pp. 71–86, ELI: http://data.europa.eu/eli/dir/2009/128/oj)

minor uses and for authorisations by mutual recognition in order to achieve more harmonised availability of plant protection products for minor uses.

(24) Experience has shown that the provisions in Regulation (EC) No 1107/2009 related to the protection of data in test and study reports submitted for the authorisation of plant protection products are complex and create barriers to market entry for new suppliers of plant protection products and unequal distribution and different costs of plant protection products depending on the size of the Member States, thus creating unfair competition between plant protection product manufacturers and farmers. Furthermore, the data protection regime lacks transparency in terms of when data protection for a given test or study report expires in the different Member States, in particular for studies or tests used for renewals of approvals or extensions of authorisations for minor uses. The relevant provisions should therefore be amended to set the same data protection period for a given study or test across the Union to increase transparency and facilitate market access for alternative suppliers to increase the availability of plant protection products at comparable costs to farmers independent from the Member States where they are established.

(25) The obligation of the Member States under Article 68 to transmit to the Commission reports on the official controls on the enforcement of Regulation (EC) No 1107/2009 has already been superseded by the obligation to transmit annual reports under Article 113(1) of Regulation (EU) 2017/625. Thus Article 68 should be deleted in order to avoid confusion and unnecessary administrative burden for the Member States.

(26) Transitional provisions are necessary in order to ensure a smooth transition for the pending approval and renewal procedures for active substances used in plant protection products, so that they are completed under the current rules but the approval period is granted under the new rules. A transitional provision is also necessary in order to ensure that a test or study report whose data protection started under the old rules does not get double protection in the same Member State under the new EU wide rules. It is further clarified that all basic substances approved at the entry into force of this Regulation could be placed on the market independent of their approval as regular active substances in order to ensure equal treatment and fair competition for all basic substances and for all farmers independent from the Member State they are based.

[…] N.B. Recitals 27-63 ((MRL, Reg. 396/2005, biocides, Reg. 528/2012, and recitals regarding cluster C) are addressed separately

HAVE ADOPTED THIS REGULATION:

PUBLIC

Article 1

Amendments to Regulation (EC) No 1107/2009

Regulation (EC) No 1107/2009 is amended as follows:

(1) Article 2 is amended as follows

(a) paragraph 1, point (b) is replaced by the following:

‘ (b) ‘ regulating life processes of plants, such as substances regulating their growth, other than as a nutrient or a plant biostimulant**,** ;‘;

(b) paragraph 2 is replaced by the following:

‘2. This Regulation shall apply to substances, including biocontrol substances, having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as ‘active substances.’;

(2) Article 3 is amended as follows:

(a) point 17 is replaced by the following:

‘17. ′zone′ means a group of Member States as defined in Annex I.

For the purpose of use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment, for uses that are solely and explicitly needed in order to prevent the entry into, and spread within, the Union, of pests listed in accordance with Articles 5(2), 30(1), 32(3), 37(2) of Regulation (EU) 2016/2031 and for plant protection products containing as active substances only ~~biocontrol or~~ low-risk active substances, the zone means all zones defined in Annex I.’;

(aa) point 27 is replaced by the following:

‘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;’;

(b) point 34 is replaced by the following:

‘34. ‘plant biostimulant’ means a product having at least one of the following actions:

(1) stimulating plant nutrition processes independently of the product’s nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

(a) nutrient use efficiency;

(b) quality traits;

(c) availability of confined nutrients in soil or rhizosphere;

(2) stimulating life processes of crops to improve their tolerance to abiotic stress.

Substances regulating life processes of crops whose effect in the plant are not directly related to better nutritional intake or a nutritional function, but rather by mimicking, inhibiting, or otherwise interfering with endogenous plant hormonal signalling pathways which are not fulfilling the definition of plant biostimulants are active substances covered by this Regulation.’;

(c) the following point 35 is added:

‘35. ‘biocontrol substance’ means :

(a) micro-organisms,

PUBLIC

(b) inorganic substances as occurring in nature, with the exception of heavy metals and their salts,

(c) substances of biological origin or produced synthetically that are functionally and structurally identical to them, or

(d) substances of biological origin or produced synthetically that are functionally identical and structurally similar to them, and meet the criteria set out in Annex II point 5 to this Regulation.';

PUBLIC

(d) the following point 36 is added:

'36. ´basic substances´ means active substances that are not predominantly used for plant protection purposes, including foodstuffs and substances evaluated in accordance with other Union legislation, but are nevertheless useful in plant protection.';

(3) in Article 4, paragraph 7 is replaced by the following:

'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 rapporter 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.

The evidence referred to in the first subparagraph shall be submitted during the approval proccess, 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.

PUBLIC

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~~.

';

(4) Article 5 is replaced by the following:

'*Article 5*

First approval

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

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

~~(b) active substances that are approved under Article 4(7); or~~

~~(c) active substances for which a limited period of approval is set in accordance with Article 6 point (j), in particular in the light of relevant uncertainties emerging from the risk assessment, including as a result of data gaps.~~

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

'1. An application for the approval of an active substance, for an amendment of the conditions of approval, or for a change of status for an active substance as identified in the regulation referred to in Article 13(4), shall be submitted by the producer of the active substance to a Member State (the "rapporteur Member State") together with a summary and a complete dossier as provided for in Articles 8(1) and (2) of

this Regulation or a scientifically reasoned justification for not providing certain parts of those dossiers. The application shall demonstrate that the active substance fulfils the approval criteria provided for in Article 4 of this Regulation or, where applicable, that the change of status of the active substance is justified. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002 of the European Parliament and of the Council, which shall apply mutatis mutandis.

A joint application may be submitted by an association of producers designated by the producers for the purpose of compliance with this Regulation.

The application shall be examined by the Member State proposed by the applicant, unless another Member State agrees to examine it.

By way of derogation from the first subparagraph, applications for the approval of biocontrol substances may be submitted to the Authority which shall assume the duties of the rapporteur Member State.';

(6) Article 11 is amended as follows:

(a) the following paragraph 1a is inserted:

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

(b) in paragraph 2, the following subparagraph is added:

'The rapporteur Member State may ask the Authority to provide technical and scientific support during the assessment required for the preparation and delivery of the draft assessment report, during the assessment of the additional information referred to in Article 12(3), and for the preparation of necessary updates of the draft assessment report after its initial submission.';

(7) in Article 13, paragraph 4 is replaced by the following:

'4. Approved active substances shall be included in the Regulation referred to in Article 78(3) containing the list of active substances already approved. The Commission shall maintain a list of approved active substances electronically

available to the public. This list shall indicate whether an active substance is a biocontrol substance **.**';

(8) the heading of Subsection 3 is replaced by the following:

'Subsection 3

Renewal, reassessment and review';

(9) Article 14 is replaced by the following:

'*Article 14*

Renewal of approval

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

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

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

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

~~active substances shall be for an unlimited period, except for:~~

~~(a) active substances that are approved as candidates for substitution in accordance with Article 24,~~

~~(b) active substances whose approvals are renewed under Article 4(7); or~~

PUBLIC

~~(c) active substances for which a limited period of renewal is set in accordance with Article 6, point (j), in particular in the light of relevant uncertainties emerging from the risk assessment including as a result of data gaps.~~

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

(10) ~~Article 18 is replaced by the following:~~

~~'*Article 18*~~

~~**Work programme for renewal of approval of active substances with unlimited approval periods**~~

~~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.~~

~~The Commission shall, at least every two years, after consulting the Authority, assess the need to set a work programme by way of an implementing act identifying active substances or groups of active substances with unlimited approval periods for which a renewal procedure shall be conducted. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 79(3).~~

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

~~The Commission shall adopt an implementing act identifying all relevant active substances, as referred to in the first subparagraph, at the latest 3 years after amendments to the approval criteria set out in Annex II relevant for these active substances, or when updated data requirements or guidance documents relevant for these active substances become applicable.~~

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~~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, in the case of biocontrol substances, the Authority;~~

~~(c) set deadlines for the submission of applications for renewal of the approval of the active substances concerned that allow sufficient time for the generation of the necessary data and the submission of the said applications; and~~

~~(d) set expiry dates for the approvals of the active substances concerned that allow sufficient time for the submission and evaluation of the applications and for the adoption of decisions on the renewal of the approval of the active substances concerned.~~

~~3. Articles 14, 15(2), 16, 17 and 20 shall apply.';~~

(11) The following article 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, met.

It may, after consulting the Authority, and in accordance with the procedure referred to in Article 79(3), adopt implementing acts identifying active substances or groups of active substances with limited or unlimited approval periods for targeted reassessment.

The identification of the active substances concerned shall **take into account indications of safety concerns for human or animal health or the environment, new scientific or technical knowledge and available monitoring data and may**

take into account requests from Member States ~~be based on the same criteria as laid down in Article 18(1)~~.

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.'

PUBLIC

(12) Article 19 is replaced by the following:

'*Article 19*

Implementing measures

The Commission shall adopt an implementing act, in accordance with the procedure referred to in Article 79(3), setting out the provisions necessary for the implementation of the renewal procedure and of the targeted reassessment procedure, as provided for in this Subsection 3.';

(13) in Article 20, paragraph 2 is replaced by the following:

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

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

(14) Article 22, paragraphs 1 and 2 are replaced by the following:

'1. An active substance complying with the criteria provided for in Article 4 and in point 5 of Annex II shall be approved as a low-risk active substance.

2. Articles 4 to 21 shall apply. Low-risk active substances shall be listed separately in the Regulation referred to in Article 13(4).';

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(15) Article 23 is replaced by the following:

'*Article 23*

Approval criteria for basic substances

1. An approval granted pursuant to this Article and Article 23a shall cover:

(a) the direct use of the basic substance for plant protection purposes as such or when produced by the user directly from plants or parts of plants after simple preparation;

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

(c) Any product containing a basic substance with a composition not complying with point (b) of the first subparagraph shall be considered as a plant protection product and shall require an authorisation in accordance with Chapter III.

2. By way of derogation from Article 4, the basic substance shall be approved where all the following criteria are fulfilled:

(a) the basic substance is not a substance of concern or the hazard classification of the substance in accordance with Regulation (EC) No 1272/2008 does not apply to the product in which it is approved for use;

(b) the basic substance and the product in which it is used does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects and is not carcinogenic, mutagenic or toxic for reproduction;

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(c) is not an approved active substance for use in plant protection products at the time of the submission of the application for approval as basic substance and no application for an approval as an active substance is under assessment at that moment;

(d) the basic substance or the product in which it is used has neither immediate or delayed harmful effects in human health, including that of vulnerable groups, or animal health, nor unacceptable effects on the environment and there is no need for setting maximum residue levels, arising from its use(s) for plant protection purposes.';

(16) The following article is inserted:

'*Article 23a*

Approval procedure and labelling of basic substances

1. By way of derogation from Article 7, an application for the approval of a basic substance shall be submitted by a Member State or by any interested party to the Commission.

The application shall be accompanied by the following information:

(a) intended uses and proposed conditions of use of the basic substance;

(b) any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other Union legislation regulating the use(s) of the substance; and

(c) other relevant information on its possible effects on human or animal health or the environment.

2. The Commission shall ask the Authority for an opinion or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within 3 months of the date of the request.

3. Articles 6 and 13 shall apply. Basic substances shall be listed separately in the Regulation referred to in Article 13(4).

4. The approval shall cover all approved uses of the basic substances and any product containing it as specified under Article 23(1). The approval shall be for an unlimited period and Articles 59 to 62 shall not apply.

5. Where a substance approved as a basic substance is subsequently also approved as an active substance that is not a basic substance, that approval shall not affect the existing approval as a basic substance, as well as the placing on the market and use as basic substance or product as referred to in Article 23(1)**.**

6. Any applicant may request an extension of the approved uses of a basic substance. Paragraphs 1 to 4 apply. Where justified in the light of the outcome of the evaluation, the Commission shall update the review report for the basic substance, including a reference to the applicable review report in the approval regulation.

7. The Commission may review the approval of a basic substance at any time. It may take into account the request of a Member State to review the approval.

Where the Commission considers that there are indications that the substance no longer satisfies the criteria provided for in paragraph 2 of Article 23 it shall inform the Member States, the Authority and the interested party, setting a period for their comments to be submitted.

The Commission shall ask the Authority for an opinion, or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within three months of the date of the request.

Where the Commission concludes that the criteria referred to in paragraph 1 are no longer satisfied, a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3).

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8. Basic substances and products referred to in Article 23(1) may be labelled as "Products containing (a) basic substance(s) for plant protection". In such case the label shall contain, but not go beyond, clear and comprehensive indications about their allowed use for plant protection and the approval conditions and restrictions. In case the basic substance or product refered to in Article 23(1) is placed on the market specifically for plant protection purposes, the labelling is mandatory and uses outside of plant protection do not need to be mentioned on the packaging.

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

(17) The following article is inserted:

'*Article 27a*

Approval periods of active substances already ~~granted approvals~~ approved on [the date of entry into force of this Regulation]

1. For ~~all~~ **low-risk** active substances approved at the latest on (…) [*OP please insert the date of entry into force of this Regulation]*, approvals shall be deemed unlimited in time, except for:

(a) ~~active substances identified as candidates for substitution in accordance with Article 24;~~

(b) ~~active substances approved under Article 4(7);~~

(c) **low-risk** active substances for which the submission of an application for renewal under Article 15(1) was required before *[OP: please insert the date of entry into force of this Regulation]* but was not submitted before the deadline referred to in Article 15(1);

(d) **low-risk** active substances for which a procedure for the renewal of approval is ongoing on *[OP: please insert the date of entry into force of this Regulation];*

2. The Commission shall amend the Regulation referred to in Article 78(3) in accordance with the first paragraph.

3. **For active substances for which no renewal procedure is ongoing on** *[OP: please insert the date of entry into force of this Regulation],* **the Commission shall amend the Regulation referred to in Article 78(3) to extend their approval period by 5 years**.';

(18) in Article 28, paragraph 2 is amended as follows:

(a) point (a) is replaced by the following:

'(a) placing on the market and use of basic substances or products referred to in Article 23(1).';

(b) the following point**s** are added:

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

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

(19) Article 30 is replaced by the following:

'*Article 30*

Provisional authorisations for plant protection products containing ~~biocontrol~~ low-risk active substances

1. By way of derogation from Article 29(1), point (a), Member States may authorise for a provisional period not exceeding five years, the placing on the market of plant protection products containing **only** ~~one or more biocontrol~~ active

substances **expected to meet the criteria set out in Annex II point 5 to this Regulation** not yet approved, provided that

(a) the dossier is admissible in accordance with Article 9 and the Rapporteur Member State has finalised the draft assessment report in accordance with Article 11 concluding that the not yet approved ~~biocontrol~~ active substances in the plant protection product are expected to satisfy the requirements of Article 4(2) and Article 4(3) **and the criteria set out in Annex II point 5 to this Regulation** ;

(aa) the Authority has launched a public consultation thereupon;

(b) the Member State concludes that all active substances in the plant protection product comply with the criteria of point 5 of Annex II ~~or qualify as biocontrol active substance~~ and that the uses of the plant protection product for which provisional authorisations are granted satisfy the requirements of Article 29(1), points (b) to (h);

(c) where relevant, maximum residue levels have been established in accordance with Regulation (EC) No 396/2005.

2. When a Member State grants a provisional authorisation in accordance with paragraph 1, that Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorisation, providing at least the information listed in Article 57(1).

3. Article 44 applies to provisional authorisations granted in accordance with paragraph 1.

4. Following the approval of an active substance contained in a plant protection product for which a Member State has granted a provisional authorisation in accordance with this Article, the Member States may transform the provisional authorisation into an authorisation granted in accordance with Article 36, unless the conditions set in the approval require amendment of the provisional authorisation.';

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(20) Article 32 is replaced by the following:

'*Article 32*

Duration

1. The period of authorisation shall be laid down in the authorisation.

Without prejudice to Article 44, the duration of an authorisation shall be set for a period not exceeding 1 year from the date of expiry of the approval of the active substances, safeners and synergists contained in the plant protection product and thereafter for as long as the active substances, safeners and synergists contained in the plant protection product are approved.

This period shall allow the examination as provided for in Article 43 to be carried out.

Without prejudice to Article 44, authorisations shall be valid for an unlimited time if the plant protection product concerned contains **as active substances** only **low-risk** active substances~~, safeners, and synergists~~ with unlimited approval periods, **and does not contain safeners or synergists,** and the plant protection product has been assessed according to this Regulation considering the latest assessments underlying the approvals of the **concerned low-risk** active substances, ~~safeners, and synergists~~ contained in the product.

~~Authorisations shall be valid for a limited time if the plant protection product concerned contains at least one active substance, safener or synergist with a limited approval period. Without prejudice to Article 44, the duration of such an authorisation shall be set for a period:~~

~~(a) […]~~

~~(b) not exceeding 1 year from the earliest date of expiry of the approval of the active substances, safeners and synergists contained in the plant protection product concerned and thereafter for as long as the active substances, safeners and synergists contained in the plant protection product remain approved.~~

~~This period shall allow the examination as provided for in Article 43 to be carried out.~~

2. Authorisations may be granted for shorter periods to synchronise the re-evaluation of similar products for the purposes of a comparative assessment of products containing candidates for substitution as provided for in Article 50.';

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

'(b) a proposal as to which Member State the applicant expects to evaluate the application in the zone concerned. In the case of an application for use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment, for uses that are solely and explicitly needed in order to prevent the entry into, and spread within, the Union, of pests listed in accordance with Articles 5(2), 30(1), 32(3) and 37(2) of Regulation (EU) 2016/2031 and for a plant protection product containing as active substances only ~~biocontrol or~~ low-risk active substances, only one Member State shall be proposed, which evaluates the application taking account of all zones. In this case the applicant shall send the summary or complete dossier as referred to in Article 8 to other Member States on request.';

(22) in Article 36, paragraph 1, the first subparagraph is replaced by the following:

'1. The Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents **approved /endorsed** ~~available~~ at the time of the application. It shall give all Member States in the same zone the opportunity to submit comments to be considered in the assessment.

For the active substances, safeners and synergists contained in the plant protection product, Member States shall rely on the last assessment conducted at EU level unless it considers that an update is necessary in the light of the current scientific and technical knowledge. In this case the Member State shall request the Commission to act under Articles ~~18,~~ 18a or 21.';

(23) in Article 37, the following paragraphs are added:

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

~~5a. Where the Member States concerned need additional information before the expiry of the 120 days referred to in paragraph 5 of this Article, they shall set a period not exceeding 6 months for the applicant to submit it. In that case, the 120 day period shall be suspended. Where, at the end of the additional period, the applicant has not submitted the additional information, the Member States shall inform the applicant that the authorisation is not granted.~~

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 and/or~~ low risk substances.

7. The Member State examining an application for plant protection product uses that are solely and explicitly needed in order to prevent the entry into, and spread within, the Union, of pests listed in accordance with Articles 5(2), 30(1), 32(3) and 37(2) of Regulation (EU) 2016/2031 shall endeavour to decide as early as possible and in any case within 6 months.';

(24) Article 40 is replaced by the following:

'*Article 40*

Mutual recognition

1. The holder of an authorisation granted in accordance with Article 29 may apply for an authorisation for the same plant protection product, the same use and under comparable agricultural practices in another Member State under the mutual recognition procedure, provided for in this subsection, in the following cases:

(a) the authorisation was granted by a Member State (reference Member State) which belongs to the same zone and the authorised plant protection product is placed on the market in the reference Member State;

(b) the authorisation was granted by a Member State (reference Member State) which belongs to a different zone provided that the authorisation for which the application was made is not used for the purpose of mutual recognition in another Member State within the same zone and the authorised plant protection product is placed on the market in the reference Member State;

(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 or~~ low risk active substances 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.

2. Where a plant protection product is not authorised in a Member State because no application for an authorisation has been submitted in that Member State, official or scientific bodies involved in agricultural activities or professional agricultural organisations may apply for an authorisation for the same plant protection product, the same use and under the same agricultural practices in that Member State under the mutual recognition procedure referred to in paragraph 1.';

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(25) Article 42 is replaced by the following:

'*Article 42*

Procedure

1. The application shall be accompanied by the following:

(a) a copy of the authorisation granted by the reference Member State as well as a translation of the authorisation into an official language of the Member State receiving the application;

(b) a formal statement that the plant protection product is identical to that authorised by the reference Member State, as well as evidence that the product has already been placed on the market in the reference Member State;

(c) a complete or summary dossier as required in Article 33(3) when requested by the Member State;

(d) an assessment report of the reference Member State containing information on the evaluation and decision on the plant protection product.

Points (c) and (d) shall not apply to applications submitted under Article 40(2) and Article 51(7) .

2. The Member State to which an application under Article 40 is submitted shall decide on the application within 120 days.

3. Where the application concerns a plant protection product containing as active substance only biocontrol or low-risk active substances and the Member State has not adopted a decision after 120 days, the authorisation shall be deemed as having been granted by the Member State, **unless such a principle of administrative tacit agreement does not exist in the national legal system of the other Member State concerned.** In ~~such~~ case **the authorisation is deemed to be granted**, the Member State shall **issue** ~~grant~~ the authorisation, send it to the applicant and inform of the publication of this information on the authorised plant protection product in accordance with Article 57(1), in particular the authorisation number. **Member**

States whose the national legal system does not allow the application of tacit approval shall inform the Commission thereof by [*12 months from entry into force of this Regulation*].

~~3a. Where the Member State needs additional information before the expiry of the 120 day period referred to in paragraphs 2 and 3 of this Article, it shall set a period not exceeding 6 months for the applicant to submit it. In that case, the 120 day period shall be suspended. Where at the end of the additional period, the applicant has not submitted the additional information, the Member State shall inform the applicant that the authorisation is not granted.~~

4. Where requested by the Member State, the applicant shall submit the application in the national or official languages of that Member State or one of those languages.

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

(26) […]

(27) […]

(28) […]

(29) […]

(30) […]

(30a) The heading of Subsection 4 is replaced by the following

'Subsection 4

Renewal, reassessment, withdrawal and amendment';

(30 b) The following article 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 Regulation confirming 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.'

(31) Article 46 is replaced by the following:

'*Article 46*

Grace period

1. Where a Member State withdraws or amends an authorisation or does not renew it, as a result of a Regulation adopted pursuant to Article 20(1) or as a result of a Regulation adopted pursuant to Article 21(3), Member States shall set a grace period within the limits of the maximum grace period set by the Commission on the basis of Article 20(2), unless the Commission has prohibited the setting of such a grace period on the basis of Article 20(2) .

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 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.';

(32) Article 49 is replaced by the following:

'*Article 49*

Placing on the market of treated seeds ~~and~~ or other plant reproductive material

1. The treatment of seeds ~~and~~ **or other** plant reproductive material with plant protection products is a use of a plant protection product.

2. Placing on the market and use of seeds ~~and~~ **or other** plant reproductive material treated with a plant protection product which is not authorised in any Member State is prohibited.

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2a. Member States may allow seeds ~~and~~ or other plant reproductive material treated with plant protection products whose authorisation has been withdrawn or amended after the time of treatment to be used for sowing or planting provided that such seeds and plant reproductive material comply with the requirements of Union legislation on plant reproductive material, unless a different period for sowing or planting has been laid down in the withdrawal or amendment of the authorisation.

3. Member States can only prohibit the placing on the market or the use of seeds ~~and~~ **or other** plant reproductive material treated with plant protection product authorised for that use in at least one Member State if there are substantial concerns that treated seeds are likely to constitute a serious risk to human or animal health or to the environment and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned.

4. In the cases referred under paragraph 3 above, the Commission may take measures to restrict or prohibit the use and/or sale of such treated seeds and plant reproductive material in accordance with the procedure referred to in Article 79(3). Before taking such measures, the Commission shall examine the evidence and may request an opinion from the Authority. The Commission may set a time limit within which such an opinion shall be provided.

5. Articles 70 and 71 shall apply.

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6. Without prejudice to other Union legislation concerning the labelling of seeds ~~and~~ **or other** plant reproductive material, the label and documents accompanying the treated seeds ~~and~~ **or other** plant reproductive material shall include the name of the plant protection product with which they were treated, the ~~date~~ **year** of treatment, its authorisation number and the Member State which authorised it, the name(s) of the active substance(s) in that product, hazard statements and precautionary statements as provided for in Regulation (EC) No 1272/2008 and the implementing act adopted under Article 65(1) and, where applicable, risk mitigation measures set out in the authorisation for that product.

6a. Detailed rules for the implementation of Article 49 may be established in accordance with the procedure referred to in Article 79(3).';

(33) Article 51 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. Member States shall extend the authorisation provided that all the following conditions are met:

(a) the intended use is minor in nature;

(b) the conditions provided for in Article 4(3), points (b), (d) and (e), and Article 29(1)(i) are fulfilled;

(c) the documentation and information to support the extension of use has been submitted by the persons or bodies referred to in paragraph 1 or is available otherwise, in particular data on the magnitude of residues and where necessary on the risk assessment as regards the operators, workers and bystanders.'

(b) paragraph 3 is replaced by the following:

'3. Member States shall take measures to facilitate or encourage the submission of applications to extend the authorisation of already authorised plant protection products to minor uses.';

(c) paragraph 7 is replaced by the following:

'7. The applicants referred to in paragraph 1 may also apply for authorisation of a plant protection product for minor uses in accordance with Article 40(1) even if the uses in the reference Member State are not minor uses. Member States shall authorise such uses in accordance with Article 41.';

(d) paragraph 9 is replaced by the following:

'9. Detailed rules for the implementation of this Article 51 may be established in accordance with the procedure referred to in Article 79(3).';.

(34) 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

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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.

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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 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 Articles 43 **and 43a** in any Member State or from the first conclusion of a review conducted in accordance with Article 44 in any Member State. Paragraphs 1 to 5 of this Article shall apply *mutatis mutandis*.

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).';

(35) in Article 67, paragraph 1 is replaced by the following:

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

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

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

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

(36) Article 68 is deleted.

(36a) The following Article is inserted:

Article 81a

Transitional provisions concerning Regulation *[OP: please insert the reference of this Regulation]*

(1) Article 14(2) as amended by *[OP: please insert the reference of this Regulation]* shall, following completion of the renewal procedure, also apply to active substances for which an application for renewal of approval has been submitted before *[date of entry force of this Regulation]*.

(2) Article 59 as it stood before being amended by Regulation *[OP: please insert the reference of this Regulation]* shall continue to apply to test and study reports whose data protection period in a Member State started before (…) *[OP please specify the entry into force of this Regulation*]. Article 59 as amended by Regulation *[OP: please insert the reference of this Regulation]* shall apply, with the exception of Article 59(3), last sentence, to those test or study reports as of the date of their first submission for the authorisation in a plant protection product in any other Member State after (…) *[OP please specify the entry into force of this Regulation*] but shall not cover the Member States referred to in the previous sentence.

(3) Article 23a (5) as amended by *[OP: please insert the reference of this Regulation]* shall also apply to all basic substances approved before the entry into force of this Regulation.'.

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[…]

N.B. Articles 3-4 (MRL, Reg. 396/2005, and biocides, Reg. 528/2012) and Articles 5-11 (cluster C) are addressed separately.

Article 12

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

[…] subparagraph 2 relates to cluster C

This Regulation shall be binding in its entirety and directly applicable in all Member States

Done at Strasbourg,

For the European Parliament	*For the Council*
The President	*The President*

PUBLIC