Council of the European Union
General Secretariat

Brussels, 03 March 2026

Interinstitutional files:
2025/0409 (COD)
2025/0410 (COD)

WK 1056/2026 ADD 5

LIMITE

SIMPL	**DENLEG**
ANTICI	**MI**
AGRI	**FOOD**
AGRILEG	**FEED**
ENV	**SEMENCES**
PESTICIDE	**SAN**
PHYTOSAN	**CHIMIE**
VETER	**CODEC**

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Comments from SE on Omnibus X: Food and feed safety _Cluster B (Pesticides related issues) - (DDL on 22 January 2026 COB)

Following the written consultation on Omnibus X – Food and Feed Safety – Cluster B (Pesticides related issues) launched on 12 January 2026, delegations will find the comments from **SE** for Cluster B.

Food and feed Omnibus Cluster B (Pesticides related issues) Deadline: ***19 January 2026***

Guidelines to be followed

Please kindly provide your contributions in the table below.

Drafting suggestions: you may use '**track changes**'* or formatting (for example **bold-underline** for additions and ~~strike-through~~ for deletions, **where necessary, in a different colour**). *Track changes can only be connected once the cursor is placed in editable areas (Drafting or Comments columns).

To make it feasible to consolidate all contributions, the structure of the table must not be changed, so **no rows can be added or deleted.**

New provisions may only be added in any of the **'existing cells'.**

Name of document: please add the **two initials** of your delegation's country followed by a space (to the MS Word document name), followed by any optional text, for example, for Austria: **AT comments on … .docx**

Thank you for your cooperation!

Commission proposal	Drafting suggestions	Comments
General Comments		
Proposal for a		
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL		
amending Council Directive 98/58/EC and Directive 2009/128/EC of the European Parliament and of the Council as regards the simplification and strengthening of food and		

Commission proposal	Drafting suggestions	Comments
feed safety requirements, and repealing Council Directives 82/711/EEC and 85/572/EEC		
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2), Article 114 and Article 192(1) thereof,		
Having regard to the proposal from the European Commission,		
After transmission of the draft legislative act to the national parliaments,		
Having regard to the opinion of the European Economic and Social Committee,		
Having regard to the opinion of the Committee of the Regions,		
Acting in accordance with the ordinary legislative procedure,		
Whereas:		

Commission proposal	Drafting suggestions	Comments
(1) Directive 2009/128/EC of the European Parliament and of the Council[1] lays down the legal framework for the sustainable use of pesticides (plant protection products). Article 9(1) of Directive 2009/128/EC provides for a prohibition of aerial spraying of pesticides by an aircraft. Article 9(2) to (6) thereof allows individual derogations from that prohibition, under certain conditions. 1 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).		
(2) Since the entry into force of Directive 2009/128/EC, experience has shown that the procedure for individual derogations from the prohibition of aerial spraying of pesticides entails considerable administrative burden for professional users and it slows down and restricts the development of technologies that could allow for safer choices for human health and the environment. Certain types of unmanned aircraft systems (commonly referred to as drones) under particular conditions are capable of minimising the exposure of the operator to the use of pesticides in the field and could allow professional users to apply pesticides in more targeted ways. Such unmanned		

Commission proposal	Drafting suggestions	Comments
aircraft systems are likely to help reduce the use of pesticides and consequently help reduce the risks to human health and the environment compared to the use of land-based application equipment. It is therefore appropriate to enable Member States to exempt such types of unmanned aircraft systems from the prohibition of aerial spraying provided for in Directive 2009/128/EC under certain conditions.		
(3) In order to ensure protection of human health and the environment, it is appropriate to require that such exemption can only apply if the pesticides are explicitly authorised for aerial use by unmanned aircraft systems. Such explicit authorisation of pesticides for aerial use by unmanned aircraft systems would ensure that any potential risks to human health and the environment from exposure to such pesticides are thoroughly assessed as part of the authorisation process. As the authorisations of pesticides are regulated under Regulation (EC) No 1107/2009 of the European Parliament and of the Council[2], the Commission should mandate the European Food Safety Authority (EFSA) to develop a guidance document on risk assessment of pesticides for application by unmanned aircraft systems under Regulation (EC) No 1107/2009 in order to ensure that a robust framework of safeguards is in place. 2 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009		

Commission proposal	Drafting suggestions	Comments
concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC OJ L 309, 24.11.2009, pp. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj).		
(4) The legislative framework governing the operation of unmanned aircraft systems includes such acts as Regulation (EU) 2018/1139 of the European Parliament of the Council[3] and Commission Implementing Regulation (EU) 2019/947[4]. This legislative framework does not identify the types of unmanned aircraft systems that could be appropriate for use for aerial application of pesticides by professional users. Therefore, complementary to the development of specific guidance on the risk assessment of pesticides that could be used for application by unmanned aircraft systems, it is necessary to identify the types of unmanned aircraft systems that have lower or equal risks as regards human health and the environment compared to the risks arising from land-based application equipment for the same use. 3 Regulation (EU) 2018/1139 of the European Parliament of the Council on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and		

Commission proposal	Drafting suggestions	Comments
repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, pp. 1, ELI: http://data.europa.eu/eli/reg/2018/1139/oj). 4 Commission Implementing Regulation (EU) 2019/947 of 24 May 2019 on the rules and procedures for the operation of unmanned aircraft (OJ L 152, 11.6.2019, ELI: http://data.europa.eu/eli/reg_impl/2019/947/oj).		
(5) In order to identify the types of unmanned aircraft systems that may be used for application of pesticides, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of supplementing Directive 2009/128/EC to identify the types of unmanned aircraft systems that have lower or equal risks compared to the risks arising from land-based application equipment for the same use. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council should receive all		

Commission proposal	Drafting suggestions	Comments
documents at the same time as Member States' experts, and those experts should systematically have access to meetings of Commission expert groups dealing with the preparation of such delegated acts.		
(6) Given the need to address perceived remaining knowledge and data gaps before the types of unmanned aircraft systems that have lower or equal risks compared to the risks arising from land-based application equipment for the same use can be identified, it is appropriate to allow time for the Commission to consult EFSA and the Member States in preparation of a delegated act identifying those types of unmanned aircraft systems that may be exempted from the prohibition of aerial spraying. The Commission should be empowered to adopt a delegated act in accordance with Article 20a to identify types of unmanned aircraft systems for which it can be established that the risks from exposure to pesticides to human health and the environment is equal to or lower than from the use of land-based application equipment for the same use. Adoption of this delegated act should be a precondition for the possibility for Member States to exempt such types of unmanned aircraft systems from the prohibition of aerial spraying. Pending the identification of the types of unmanned aircraft systems that may be exempted and the decision by a Member State to exempt those identified unmanned aircraft systems from the prohibition on		

Commission proposal	Drafting suggestions	Comments
aerial spraying, it is appropriate to continue to require a professional user to submit requests for approval of aerial spraying by all unmanned aircraft systems.		
[…] *N.B. Recitals 7-8 (in relation to Directive 98/58/EC, Council Directives 82/711/EEC and 85/572/EEC) are covered by the consultation on cluster C.*		
HAVE ADOPTED THIS DIRECTIVE:		
Article 1		
Amendments to Directive 2009/128/EC		
Directive 2009/128/EC is amended as follows:		
(1) Article 3 is amended as follows:		
(a) point 5 is replaced by the following:		

Commission proposal	Drafting suggestions	Comments
'5. 'aerial spraying' means application of pesticides from a manned aircraft or an unmanned aircraft system;';		
(b) the following point 5a is inserted:		
'5a. 'unmanned aircraft system' means any aircraft with equipment for aerial application of pesticides, operating autonomously or piloted remotely without a pilot on board;';		
(2) Article 9 is amended as follows:		
(a) in paragraph 1, the following new subparagraph is added:		
'The prohibition provided for in the first subparagraph may only be derogated from in accordance with paragraphs 2 to 6 of this Article or with Article 9a.'		
(b) in paragraph 2, the first sentence of the first subparagraph is replaced by the following:		

Commission proposal	Drafting suggestions	Comments
'2. By way of derogation from paragraph 1, aerial spraying may be allowed in special cases provided the following conditions are met:';		
(3) the following new Article 9a is inserted:		
'Article 9a		
Aerial spraying of pesticides by unmanned aircraft systems		
1. By way of further derogation from Article 9(1), Member States may, in the case of professional users, exempt from the prohibition laid down in that Article, the aerial spraying of pesticides by unmanned aircraft systems identified pursuant to paragraph 2.		
Pesticides to be used for aerial spraying by such unmanned aircraft systems shall be explicitly authorised for that use by the Member State under Regulation (EC) No 1107/2009 following a specific assessment addressing risks from aerial spraying.	Pesticides to be used for aerial spraying by such unmanned aircraft systems shall be explicitly authorised for that use by the Member State under Regulation (EC) No 1107/2009 following a specific assessment addressing risks from aerial spraying**, or covered by a an authorisation for emergency situations according to article 53 or a permit for each experiment or test under Article 54 of Regulation (EC) No 1107/2009, for aerial spraying.**	SE: Sweden supports that areal spraying shall only be performed with plant protection products explicitly authorised or permitted for such use. To clarify that emergency authorisations should also be possible to authorise we propose that this is stated in the article. To be able to perform necessary studies, experiments and tests shall be allowed if the explicit use has been given a permit in accordance with article 54 of 1107/2009 but only permitted as

Commission proposal	Drafting suggestions	Comments
		single experiments, and not authorised as programmes for series of experiments or tests.
2. The Commission shall adopt a delegated act by [*OP: please insert the date = 4 years after the entry into force of this Directive]* in accordance with Article 20a supplementing this Directive to identify the types of unmanned aircraft systems that have lower or equal risks compared to the risks arising from land-based application equipment for the same use.’;		
(4) Article 20a is replaced by the following:		
‘Article 20a		
Exercise of the delegation		
1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		
2. The power to adopt delegated acts referred to in Article 5(3), Article 8(7), Article 9a(2), Article 14(4) and Article 15(1) shall be conferred on the Commission for a period of *[OP: please insert the date = five years after the date of entry into force of*		

Commission proposal	Drafting suggestions	Comments
this Directive]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.		
3. The delegation of power referred to in Article 5(3), Article 8(7), Article 9a(2), Article 14(4) and Article 15(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([6]).		

Commission proposal	Drafting suggestions	Comments
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
6. A delegated act adopted pursuant to Article 5(3), Article 8(7), Article 9a(2), Article 14(4) and Article 15(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.'.		
[…] *N.B. Article 2 and 3 (amendments to Directive 98/58/EC, Council Directives 82/711/EEC and 85/572/EEC) are covered by the consultation on cluster C.*		
Article 4		
Transposition		

Commission proposal	Drafting suggestions	Comments
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 1 of this Directive by [*OP: please insert the date = 5 years after the entry into force of this Directive.*] at the latest. They shall forthwith communicate to the Commission the text of those provisions.		
2. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 2 and 3 of this Directive by [*OP: please insert the date = two years after the entry into force of this Directive.*] at the latest. When Member States adopt the provisions referred to in paragraphs 1 and 2, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.		
3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.		
Article 5		
Entry into force		

Commission proposal	Drafting suggestions	Comments
This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.		
Article 6		
Addressees		
This Directive is addressed to the Member States.		
Done at Strasbourg,		
For the European Parliament For the Council		
The President The President		

Proposal for a		

Commission proposal	Drafting suggestions	Comments
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		
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2), Article 114, Article 168(4)(b) and Article 192(1) thereof,		
Having regard to the proposal from the European Commission,		
After transmission of the draft legislative act to the national parliaments,		

Commission proposal	Drafting suggestions	Comments
Having regard to the opinion of the European Economic and Social Committee,		
Having regard to the opinion of the Committee of the Regions,		
Acting in accordance with the ordinary legislative procedure,		
Whereas:		
(1) In its Communication A Vision for Agriculture and Food[5], 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. 5 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) Ten legal acts in the area of food and feed safety are amended by this Food and Feed		

Commission proposal	Drafting suggestions	Comments
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[6] sets out the regulatory procedure for approval of active substances and authorisation of plant protection products in the Union. 6 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 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)		
(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,		

Commission proposal	Drafting suggestions	Comments
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 micro-organisms, inorganic substances as occurring in nature, with the exception of heavy metals and their salts, or 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).		
(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[7]. Thus, the scope of Regulation (EC) No 1107/2009 should be clarified to exclude substances		

Commission proposal	Drafting suggestions	Comments
which influence positively the life processes of crops, as those substances qualify as plant biostimulants from a plant physiological perspective. Substances interfering with life processes of plants and controlling the growth of the plants or parts of them, should remain in the scope of Regulation (EC) No 1107/2009. 7 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.		
(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		

Commission proposal	Drafting suggestions	Comments
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.		
(9) To accelerate the accessibility and availability to farmers of plant protection products containing new biocontrol substances, Member States should have the possibility to grant provisional authorisations for such products as soon as the draft assessment report for an application for approval has been delivered concluding that the substance can be approved. When the new 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.		

Commission proposal	Drafting suggestions	Comments
(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.		
(11) Article 67(1) of Regulation (EC) No 1107/2009 requires that professional users of plant protection products shall, for at least three years, keep records of the plant protection products they use, containing the name of the product, the time and the dose of application, the area and the crop where the plant protection product was used in order to raise the protection of human and animal health and the environment by ensuring the traceability and potential exposure, to increase the efficiency of monitoring and control and to reduce the costs of monitoring water quality. Considering that such information is less relevant for plant protection products containing biocontrol substances, and to reduce the administrative burden for farmers, the obligation to keep records should not apply to plant		

Commission proposal	Drafting suggestions	Comments
protection products containing only biocontrol substances.		
(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 criteria should therefore be simplified to only refer to 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.		
(13) The provisions related to basic substances in Regulation (EC) No 1107/2009 have proven to be unclear, which has led to disharmonised		

Commission proposal	Drafting suggestions	Comments
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.		

Commission proposal	Drafting suggestions	Comments
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 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.		

Commission proposal	Drafting suggestions	Comments
(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.		
(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 which cannot be contained by other reasonable means 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		

Commission proposal	Drafting suggestions	Comments
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		

Commission proposal	Drafting suggestions	Comments
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		

Commission proposal	Drafting suggestions	Comments
should be aligned with the maximum possible under Article 20.		
(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[8] 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		

Commission proposal	Drafting suggestions	Comments
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. 8 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).		
(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		

Commission proposal	Drafting suggestions	Comments
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. 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, 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. The measures would not create additional burden for the		

Commission proposal	Drafting suggestions	Comments
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[9] on the sustainable use of pesticides. 9 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)		
(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 minor uses and for authorisations by mutual recognition in order to		

Commission proposal	Drafting suggestions	Comments
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		

Commission proposal	Drafting suggestions	Comments
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.		
(27) Regulation (EC) No 396/2005[10] 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		

Commission proposal	Drafting suggestions	Comments
Agriculture and Food, the Commission announced it would pursue a stronger alignment of production standards applied to imported products, notably on pesticides and establish the principle, in compliance with the EU's international obligations, that the most hazardous pesticides banned in the EU for health and environmental reasons should not be allowed back to the EU through imported products. To advance on this, the Commission has launched in November 2025 a study to prepare an impact assessment that will consider the impacts on the EU's competitive position and the international implications and, if appropriate, propose amendments to the legal framework. In the meantime 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, MRLs that have been set based on good agricultural practices in third countries or Codex maximum limits may be set at the limit of quantification (technical zero). 10 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, pp. 1–16, ELI: http://data.europa.eu/eli/reg/2005/396/oj)		

Commission proposal	Drafting suggestions	Comments
(28) This concerns substances with mutagenic, carcinogenic, or reprotoxic properties as well as endocrine disruptors that may cause adverse effects in humans. Therefore, no level of residues leading to exposure of consumers should be allowed in order to ensure a high level of protection for consumers in the Union.		
(29) In addition, this concerns substances that are persistent organic pollutants (POP), persistent, bioaccumulative and toxic (PBT) substances, and very persistent and very bioaccumulative (vPvB) substances, as well as substances with endocrine disrupting properties that may cause adverse effect in non-target organisms. Persistent substances, by their very nature, resist degradation, resulting in prolonged presence in the environment. Their accumulation poses a significant threat to ecosystems, endangering biodiversity, agricultural production and food security. Endocrine disruptors, similarly, interfere with the hormonal systems of living organisms, causing detrimental effects not only to individual species, including migratory species, but also to entire ecosystems across national boundaries. Therefore, these substances create environmental concerns of a global nature that have a connection with the territory of the Union. Not allowing residues of these substances in food in the Union aligns with international efforts to combat pollution and supports global initiatives		

Commission proposal	Drafting suggestions	Comments
aimed at sustainable development and biodiversity conservation[11]. 11 Stockholm Convention on Persistent Organic Pollutants (POPs), https://www.pops.int/; Convention on Biological Diversity, https://www.cbd.int/		
(30) Where an appropriate evaluation by the Authority of the hazardous properties of the substance under Regulation (EC) No 1107/2009 is not available, the Commission should ask the Authority for an evaluation under Article 43 of Regulation (EC) No 396/2005. Furthermore, the term "import tolerance" is often misunderstood. Therefore, the term "import tolerance" should be repealed and it should be clarified that the definition of good agricultural practice applies equally to the Union and to a third country for the setting of MRLs.		
(31) When lowering MRLs under Regulation (EC) No 396/2005, a reasonable period should be allowed to elapse before the new MRLs become applicable, in order to permit Member States, third countries and food business operators to adapt themselves to the new requirements. It is recognised that fresh products, being perishable, are typically sold and consumed prior to the date of applicability		

Commission proposal	Drafting suggestions	Comments
of new MRLs. However, products with extended shelf lives, often processed, may still be on the market when the new lower MRLs become effective. To ensure legal certainty and to prevent unnecessary economic losses for farmers and food business operators, as well as to prevent food waste, it is deemed proportionate that products lawfully placed on the market in the Union before the applicable date of the new measure, and compliant with the MRLs valid at the time of their placing on the market in the Union, should be permitted to remain on the market unless food safety is compromised.		
(32) Article 16 to Regulation (EC) No 396/2005 sets out the procedure for establishing temporary MRLs based on monitoring data, with a mandatory review scheduled within a specified time frame, not exceeding ten years. However, certain MRLs based on monitoring data pertain to active substances that have not been approved in the Union for several decades, and for which residue levels have remained stable over time. Reviewing such temporary MRLs every ten years imposes an unnecessary burden on Member States, food business operators, and the Authority the Authority in terms of data generation and analysis. Given that MRLs can be reviewed at any time under Article 43 of Regulation (EC) No 396/2005, it is appropriate to foresee the establishment of MRLs based on monitoring data on a permanent basis.		

Commission proposal	Drafting suggestions	Comments
(33) The terms 'limit of determination (LOD)' used in Regulation (EEC) No 396/2005 and 'limit of quantification (LOQ)' used in international standards of laboratory analysis have the same meaning. However, the acronym 'LOD' may be confused with 'limit of detection' which has a different meaning. For clarity and to avoid confusion among food business operators and laboratories, it is appropriate to align Regulation (EC) No 396/2005 with the recognised international terminology.		
(34) Regulation (EU) No 528/2012[12] sets out the procedures for approval of biocidal active substances and authorisation and making available on the market and use of biocidal products. The completion of the review programme of existing biocidal active substances set out in Article 89 of that Regulation is significantly delayed. In order to ensure that Member States can dedicate their resources to the completion of the review programme, it is appropriate to set an unlimited duration for the approval of active substances, except for active substances meeting exclusion or substitution criteria under Articles 5(1) or 10 of that Regulation as those have properties that are of concern to human or animal health or the environment, and except for active substances for which time limits of approvals are considered necessary in the light of the outcome of the risk		

Commission proposal	Drafting suggestions	Comments
assessment conducted prior to a decision on an approval. The approval of active substances already approved should be converted into unlimited approvals following these new rules, except for active substances identified as meeting exclusion or substitution criteria under Articles 5(1) or 10 of that Regulation, active substances for which the renewal examination already started for which the renewal evaluation should continue or for which the approval should expire when no application for renewal was submitted by the deadline. A possibility should be foreseen that the Commission periodically selects a number of active substances based on specific criteria for which a renewal procedure should be triggered, while also maintaining the possibility to initiate early reviews pursuant to Article 15 of Regulation (EU) No 528/2012. Criteria for the selection of active substances subject to the renewal procedure should include, among others, relevant new or updated data requirements or guidance documents, indications of safety concerns for human or animal health or the environment, new scientific or technical knowledge and available monitoring data, and might take into account requests from Member States. 12 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, pp. 1–123, ELI: http://data.europa.eu/eli/reg/2012/528/oj)		

Commission proposal	Drafting suggestions	Comments
(35) To simplify and accelerate the procedure for adoption and publication of the decisions on applications for Union authorisation of biocidal products submitted pursuant to Chapter VIII of Regulation (EU) No 528/2012, the individual decisions should no longer take the form of Commission Implementing Regulations and be published at the EU Official Journal, but should take the form of Commission Implementing Decisions to be notified to the applicants, and only summaries of those Decisions should be published at the EU Official Journal for transparency.		SE: Sweden supports this proposal.
[…] *N.B. Recitals 36-63 (in relation to Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) 1831/2003, (EC) No 852/2004, (EC) No 853/2004, (EC) No 1099/2009, (EU) 2017/625) are covered by the consultation on cluster C.*		
HAVE ADOPTED THIS REGULATION:		

Commission proposal	Drafting suggestions	Comments
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) ‘disrupting 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:		

Commission proposal	Drafting suggestions	Comments
'17. ´zone´ means a group of Member States as defined in Annex I.		Sweden can support this proposal.
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.';		
(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;		

Commission proposal	Drafting suggestions	Comments
(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 disrupting life processes of crops 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:	**35. ‘biopesticides’** ~~‘biocontrol substance’~~ means:	SE: We are open for an approach where substances of biological origin are gathered under a common umbrella term. However, the term ‘biological control’, or ‘biocontrol’ is an already established term, widely used within for instance academia1 and competent authorities outside of EU, such as US EPA, and CAN EPA, and refers to the use of living organisms to control (harmful effects of) other living organisms. (All other natural or semi-natural agents are excluded from that definition.)The term ‘biocontrol’ is therefore not fit to be used as an overarching term to cover also semiochemicals and plant extract/botanicals. Further to this, only a

Formatted: Font: Bold

Commission proposal	Drafting suggestions	Comments
		subpart of the group 'biocontrol' would be relevant under the scope of Regulation (EC) 1107/2009, namely microorganisms (*i.e.* macroorganisms are exempted). We therefore propose to use the term 'biopesticides' as the overarching definition. Combined with other proposed simplifications for this group of substances, the broad definition risks extending regulatory simplifications to substances within this group, having undesirable properties.
(a) micro-organisms,	(a) micro-organisms,	SE: We propose to continue using the definition for 'microorganisms' that already exists under Regulation (EC) 1107/2007, i.e to mean 'any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material'.
(b) inorganic substances as occurring in nature, with the exception of heavy metals and their salts or	inorganic substances as occurring in nature, with the exception of heavy metals and their salts or	
(c) substances of biological origin or produced synthetically that are functionally identical and structurally similar to them.';	(c) substances of biological origin or **substances** produced synthetically that are functionally **and structurally** identical ~~and structurally similar~~ to them.';	SE: We consider that the proposed definition would include a substantial number of active substances that should not be regarded as 'biocontrol agents' or 'biopesticides' and that should not be subject to the proposed simplifications. For example, synthetic pyrethrins and pyrethroids, auxin-like plant hormones (e.g. 2, 4-D and MCPA), neonicotinoids, etc.

Commission proposal	Drafting suggestions	Comments
	(d) innovative biomolecules. We propose to add the following subparagraph: **A biocontrol substance shall not be a substance of concern; and shall not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects.**	SE: Further to this, it could be advantageous to take this opportunity and add a fourth group that would cover 'innovative biomolecules', such as RNAi, an area where research and development is quickly moving forward. We propose to add a similar sentence as for for basic substances, article 23, i.e. that the biocontrol substances shall not be a substance of concern; and does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects.
(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 included in the application or 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	'7. By way of derogation from paragraph 1, where on the basis of documented evidence included in the application or 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	SE: Sweden considers that this proposal would lower the level of protection for human health and the environment. There is also a risk that the incentive for companies to develop new, less hazardous active substances or non-chemical alternatives would be reduced.

Commission proposal	Drafting suggestions	Comments
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.	contained by other **available** ~~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.	It is well noted that the Commission in its Vision on For Agriculture and Food (ref) stated that it will "carefully consider any further ban of pesticides if alternatives are not yet available, unless the pesticide in question represents a threat to human health or to the environment that agriculture relies upon for its viability". The proposed change of Article 4(7), indicates that the Commission has changed its interpretation of this Article so that not only substances that fall for the so called 'cut-off criteria' would be considered for this derogation, but also substances where unacceptable risk has been identified. The changed interpretation, in combination with the proposed change to double the length of the grace periods (Articles 20 and 46) would suffice to deliver on the statement in the Vision, without opening up for economic (production) considerations. It is also worth noticing that the Commission proposal no longer requires Member States to draw up a phasing out plans.
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		SE: Sweden suggest that endocrine disruptors without a threshold should be added to the list of substances that cannot be considered for approval under article 4(7), in line with carcinogenic substances category 1B without a threshold.

Commission proposal	Drafting suggestions	Comments
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.’;	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.’;	SE: Propose amendment.
(4) Article 5 is replaced by the following:		
‘*Article 5*		SE: Sweden maintains a scrutiny reservation on Article 5.
First approval		
The first approval shall be for 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		

Commission proposal	Drafting suggestions	Comments
(c) active substances for which a limited period of approval is set in accordance with Article 6 (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) 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.		

Commission proposal	Drafting suggestions	Comments
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 added:		
‘1a. The rapporteur Member State shall give priority to the assessment of applications for approval of biocontrol substances.’;		
(b) the following subparagraph is added at the end of paragraph 2:		
‘The rapporteur Member State may ask the Authority to provide technical and scientific		

Commission proposal	Drafting suggestions	Comments
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:		

Commission proposal	Drafting suggestions	Comments
'*Article 14*		SE: Sweden maintains a scrutiny reservation on 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 of 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		

Commission proposal	Drafting suggestions	Comments
(c) active substances for which a limited period of renewal is set in accordance with Article 6 (j) in particular in the light of relevant uncertainties emerging from the risk assessment including as a result of data gaps.’;		
(10) Article 18 is replaced by the following:		
‘*Article 18*		SE: Sweden maintains a scrutiny reservation on Article 18.
Work programme for renewal of approval of active substances with unlimited approval periods		
1. The Commission shall periodically after consulting the Authority, adopt implementing acts in accordance with the procedure referred to in Article 79(3), identifying active substances or groups of active substances with unlimited approval periods for which a renewal procedure shall be conducted.		
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.		

Commission proposal	Drafting suggestions	Comments
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.		
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;		
(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		

Commission proposal	Drafting suggestions	Comments
renewal of the approval of the active substances concerned.		
3. Articles 14, 15(2), 16, 17 and 20 shall apply.’;		
(11) A new Article 18a is inserted:		
‘*Article 18a*		SE: Sweden maintains a scrutiny reservation on 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).		

Commission proposal	Drafting suggestions	Comments
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;		
(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		

Commission proposal	Drafting suggestions	Comments
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.’;		
(12) Article 19 is replaced by the following:		
‘*Article 19*		
Implementing measures		
An implementing act, adopted in accordance with the procedure referred to in Article 79(3), shall set out the provisions necessary for the implementation of the renewal procedure and of		

Commission proposal	Drafting suggestions	Comments
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 means 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.’;	In case of immediate **or** ~~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.	SE: Sweden proposes to change the 'and' to 'or', to also capture long-term effects.

Commission proposal	Drafting suggestions	Comments
(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.		SE: The Commission proposes to remove the link between Articles 22 and 47, allowing an active substance to be approved as a low-risk substance without demonstrating that the representative use assessed as part of the substance approval is of low risk. Sweden supports this proposal, as the demonstration of low risk should be part of the product assessment at national level rather than the substance approval.
2. Articles 4 to 21 shall apply. Low-risk active substances shall be listed separately in the Regulation referred to in Article 13(4).';		
(15) Article 23 is replaced by the following:		
'*Article 23*		
Approval criteria for basic substances		
		SE: Sweden notes that the proposed changes remove the ban on marketing basic substances as plant protection products, meaning that Article 23 allows for a form of simplified authorisation. Therefor, we consider it important that, more than today, requirements are set for assessing and evaluating risks, and that these risks are clearly communicated to users through the labelling of the

Commission proposal	Drafting suggestions	Comments
		basic substance. It should also be clarified that an authorisation of a basic substance must be withdrawn if the substance is subsequently approved as an active substance. This article and Article 23a need to be rewritten to make the approval criteria clear, the structure is not optimal. Our proposal is to amend Article 23 so that it only contains the approval criteria for basic substances. Furthermore, we suggest that Article 23a should include all the procedural provisions and the contents of the decision. We also propose two new articles addressing placing on the market and use of basic substances for plant protection purposes, Article 23b and 23c.
1. An approval granted pursuant to this Article and Article 23a shall cover:	~~1.~~ An approval ~~granted pursuant to this Article and Article 23a shall cover~~ **for a basic substance shall only be granted where it complies with the following requirements:**	SE: Propose amendment.
(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;	~~(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;~~	SE: Replaced by our new wordings of Article 23a(3)(a)
(b) the use of the basic substance in a product consisting of the basic substance and of, as	~~(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 stabilise the product.~~	SE: Replaced by our new Article 23b. In our opinion this is not a approval criterium, but a condition for placing on the market and use.

Commission proposal	Drafting suggestions	Comments
applicable, a simple diluent, other basic substances or substances necessary to stabilise the product.		
(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.	~~(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.~~	SE: With our proposal, the Commission's proposed (c) is superfluous.
2. By way of derogation from Article 4, the basic substance shall be approved where all the following criteria are fulfilled:	~~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;	(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~~;	SE: Our proposal is to only include any approval criteria for the basic substance, not products.
(b) the basic substance or the product in which it is used does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects;		
(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		

Commission proposal	Drafting suggestions	Comments
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, arising from its use(s) for plant protection purposes.';		
(16) a new Article 23a is inserted:		
'*Article 23a*		
Approval procedure and labelling of basic substances	Approval procedure and ~~labelling of basic substances~~ **contents of approvals**	SE: Propose amendment.
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;		

Commission proposal	Drafting suggestions	Comments
(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.		SE: The requirement that the application must be accompanied by relevant information on possible effects on human and animal health and the environment needs to be clarified through data requirements in an implementing regulation.
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).	3. ~~Articles 6 and 13 shall apply. Basic substances shall be listed separately in the Regulation referred to in Article 13(4).~~ **An approval of a basic substance shall cover:** **(a) the use(s) of the basic substance for plant protection purposes;** **(b) conditions and restrictions set in accordance with Article 6.**	SE: Propose amendment.
4. The approval shall cover all approved uses of the basic substances and any product containing it as specified under Article 23a without being limited by the uses applied for. The approval shall	4. ~~The approval shall cover all approved uses of the basic substances and any product containing it as specified under Article 23a without being limited by the uses applied for.~~ The approval shall	SE: We find the meaning of the first sentence to be unclear and is partly coverad by our proposal to Article 23a(3). The use of products is covered by our proposal to Article 23b.

Commission proposal	Drafting suggestions	Comments
be for an unlimited period and Articles 59 to 62 shall not apply.	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 refer to in Article 23(1).	**5. Article 13 shall apply. Basic substances shall be listed separately in the Regulation referred to in Article 13(4).** ~~5~~. **6.** Where a substance approved as a basic substance is subsequently also approved as an active substance that is not a basic substance, ~~that~~ **the approval as a basic substance shall be withdrawn.** ~~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 refer to in Article 23(1).~~	SE: We believe that the approval of the basic substance should be withdrawn when the substance has been approved as an active substance as the latter better fulfils the purpose of the Regulation to ensure a high level of protection of health and the environment.
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.	~~6.~~**7.** Any applicant may request an extension of the approved uses of a basic substance. Paragraphs 1 to ~~4~~**5** 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.	SE: Propose amendment.
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.	~~7.~~**8.** 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.	SE: Propose amenment.
Where the Commission considers that there are indications that the substance no longer satisfies the criteria provided for in paragraph 2 of Article		

Commission proposal	Drafting suggestions	Comments
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).		
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 clear indications about their allowed use for plant protection.	~~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 clear indications about their allowed use for plant protection~~.	SE: Covered by our proposal to Article 23c
9. Detailed rules for the implementation of this Article may be established in accordance with the procedure referred to in Article 79(3).';		

Commission proposal	Drafting suggestions	Comments
	<u>Two new articles are inserted, Article 23b and 23c:</u> ***<u>Article 23b</u>*** **<u>Placing on the market and use of formulations containing basic substances</u>** **<u>A basic substance may only be placed on the market and used for plant protection purposes, as such or in a formulation consisting of the basic substance and of, as applicable, a simple diluent, other basic substances or substances necessary to stabilise the product. Such formluations may not contain any co-formulants listed in Annex III.</u>** ***<u>Article 23c</u>***	SE: We consider that basic substances marketed as plant protection products should be labelled with both the approved uses and the restrictions and conditions of the approval. If this information is not communicated to the user, this may cause risks to human health and the environment.

Commission proposal	Drafting suggestions	Comments
	Labelling and proper use of basic substances **1. When placed on the market for plant protection purposes, basic substances, or formulations containing basic substances, shall be labelled "Contains (a) basic substance(s) for plant protection". The label shall also include the approved uses, conditions and restrictions of the approval of the basic substance.** **2. Proper use of a basic substance for plant protection purposes shall include the application of the principles of good plant protection pratice and shall be in compliance with the approved uses, conditions and restrictions of the approval of the basic substance, as specified on the labelling, or, where there is no labelling, as established in the approval.**	
(17) a new Article 27a is inserted:		
'*Article 27a*		SE: Sweden maintains a scrutiny reservation on Article 27a.
Approval periods of already granted approvals		
1. For all 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:		

Commission proposal	Drafting suggestions	Comments
(a) active substances identified as candidates for substitution in accordance with Article 24;		
(b) active substances approved under Article 4(7);		
(c) 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) 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.’;		
(18) in Article 28, paragraph 2 is amended as follows:		
(a) point (a) is replaced by the following:		

Commission proposal	Drafting suggestions	Comments
'(a) placing on the market and use of basic substances or products referred to in Article 23(1).';	'(a) placing on the market and use of basic substances or **formulations** ~~products~~ referred to in Article 23(1).';	SE: Sweden refers to its comments on Article 23(1) regarding the use of the term "products".
(b) the following point (f) is 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.';		SE: In our opinion, treated seed constitutes a treated article. Therefore, no exemption from the requirement for product authorisation is needed. If justified, treated seeds and other treated articles could instead be regulated elsewhere in Regulation 1107/2009.
(19) Article 30 is replaced by the following:		
'*Article 30*		
Provisional authorisations for plant protection products containing biocontrol active substances		SE: The potential efficiency gains of allowing temporary product authorizations for biocontrol substances while the substance evaluation is still ongoing is not obvious. Since the product authorsation takes into account an incomplete substance evaluation, it will need to be reviewed once the evaluation is finalised, which may result in some duplicate work. The proposal contains several unclarities. For example, it should be clarified that an application is required and who may submit it, as the current

Commission proposal	Drafting suggestions	Comments
		wording suggests that the Member State could initiate it on its own. It is also unclear whether data protection would start from the time the temporary authorisation is granted. It should be specified that the temporary authorisation applies to the same product and use as evaluated as a representative use. References are missing to Art. 27, regarding the requirement that affected products must not contain unacceptable co-formulants, to Art. 31, regarding the contents of the product authorization, and to Art. 37, regarding the review period. Rules for data protection of studies forming the basis of temporary authorisations must also be established.
1. By way of derogation from Article 29(1)(a), Member States may authorise for a provisional period not exceeding five years, the placing on the market of plant protection products containing one or more biocontrol active substances 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);		

Commission proposal	Drafting suggestions	Comments
(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)(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		

Commission proposal	Drafting suggestions	Comments
granted in accordance with Article 36, unless the conditions set in the approval require amendment of the provisional authorisation.'; 		
(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: 		
(a) not exceeding 15 years if the plant protection product concerned contains only active substances, safeners, and synergists with unlimited approval periods, or, 	(a) not exceeding 15 years **<u>from the first authorisation within relevant zone</u>** if the plant protection product concerned contains only active substances, safeners, and synergists with unlimited approval periods, or, 	SE: We support the proposal of regular reviews of plant protection products, as regular reviews of substances and products are essential to account for scientific developments. The scientific basis for decisions should be maintained to preserve the credibility of the system. However, there might be challenges in coordinating renewal work, as expiry dates will vary between Member States.
(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.	(b) not exceeding **<u>15 months</u>** ~~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.	SE: The one-year time limit is inconsistent with the wording of Art. 43(5), which states that applications for renewed product approval must be submitted within three months of the renewed approval of the active substance, and that the

Commission proposal	Drafting suggestions	Comments
		decision must be made within 12 months of submission. This should be amended to a period of one year and three months.
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		

Commission proposal	Drafting suggestions	Comments
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, 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 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.’;		SE: Recent judgements from the European Court of Justice have clarified that guidance documents cannot be limited to those available at the time of the application, since they are not legally binding. The Court also requires that any new scientific or technical findings that emerge during the evaluation should be taken into account. If the Commission's intention is to limit the evaluation for product authorisation strictly to the knowledge available at the time of application, more fundamental changes to Regulation (EC) 1107/2009 would be needed. SE considers that the Commission’s proposal, which we believe is an attempt to take the ECJ

Commission proposal	Drafting suggestions	Comments
		judgment into consideration, will not counter the judgement, i.e. the shift of the review of new data on active substances from the Community level to a review at Member State level as part of the product evaluation. We see a high risk that competent authorities in different MS will evaluate the same new information on the substance. In addition to inefficient use of resources, there is also a high risk for divergent outcomes and delays.
(23) new paragraphs 5, 6 and 7 are added to Article 37:		
'5. Where the application concerns a plant protection product containing as active substances only biocontrol or low-risk active substances and the Member States concerned have not adopted a decision after 120 days, the authorisation shall be deemed as having been granted by the Member States.	~~'5. Where the application concerns a plant protection product containing as active substances only biocontrol or low-risk active substances and the Member States concerned have not adopted a decision after 120 days, the authorisation shall be deemed as having been granted by the Member States.~~	SE: Sweden has identified several problematic issues with the proposed automatic approval of a product in a Member State triggered by a non-decision. In such cases, there is no formal decision established in the concerend Member State, and hence it is unclear which uses are authorised in the concerned Member State as the appcliations may differ between Member States. It is unclear whether the decision of the zonal Rapporteur Member State applies instead. The decision is not available in the language of the concerned Member State, it is unclear whether it can be appealed—and if so, to whom, and within what timeframe. The decision of the zonal Rapporteur Member State may contain labelling requirements that differ from those applicable in the concerned

Commission proposal	Drafting suggestions	Comments
		Member State, and conditions that are not adapted to national circumstances. It may also be unclear when the decision takes effect and when any grace periods begin. If the intention is for the decision to take effect once the time limit has expired, specific rules need to be introduced to address these issues. This considered we believe that Article 37(5) should be deleted.
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 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		

Commission proposal	Drafting suggestions	Comments
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:		SE: The Commission proposes that, for a product authorisation to be subject to mutual recognition, the product must be placed on the market in the reference Member State. Sweden sees practical difficulties in how this requirement is to be verified in the context of an application.
(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		

Commission proposal	Drafting suggestions	Comments
products containing as active substances only biocontrol 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.’;		
(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;		

Commission proposal	Drafting suggestions	Comments
(b) a formal statement that the plant protection product is identical to that authorised by the reference Member State;	(b) a formal statement that the plant protection product is identical to that authorised by **and marketed in** the reference Member State;	SE: The application should be supplemented with information confirming that the product is available 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.		SE: See comment on Article 37(5).

Commission proposal	Drafting suggestions	Comments
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) Article 43 is amended as follows:		
(a) paragraph 2 is replaced by the following:		
‘2. That application for renewal shall be submitted:		
(a) No later than nine months before the expiry of an authorisation, if the plant protection product concerned contains only active substances, safeners, and synergists with unlimited approval periods, or		
(b) Within 3 months from the renewal of the approval of an active substance, safener or synergist contained in the plant protection product.		
(27) The applicant shall provide the following information:		

Commission proposal	Drafting suggestions	Comments
(a) a copy of the authorisation of the plant protection product;		
(b) any new information required as a result of amendments in data requirements or criteria;		
(c) evidence that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval;		
(d) any information required to demonstrate that the plant protection product meets the requirements set out in the Regulation on the renewal of the approval of the active substance, safener or synergist contained therein;		
(e) a report on the monitoring information, where the authorisation was subject to monitoring.';		
(b) in Article 43, paragraph 5 is replaced by the following:		

Commission proposal	Drafting suggestions	Comments
(28) 'Member States shall decide on the renewal of the authorisation of a plant protection product at the latest 12 months after the submission of the application;';	(28) 'Member States shall decide on the renewal of the authorisation of a plant protection product at the latest **15** ~~12~~ months after the submission of the application;';	SE: The wording should be revised so that Member States are required to issue a decision within one year and three months of receiving the application.
(29) in Article 44, a new paragraph 1a is inserted:		
(30) '1a. Member States shall check compliance of all plant protection products containing the active substance, safener or synergist concerned with any conditions and restrictions provided for in the Regulation confirming the approval under Article 18a.';		SE: Sweden welcomes the reintroduction of a formal compliance control similar to that which existed under Directive 91/414/EEC. However, clarification is needed regarding when such checks should be carried out, alternatively, a date could be stated in the approval regulation.
(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) .		

Commission proposal	Drafting suggestions	Comments
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).’;	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. **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.**	SE: Sweden conders the Commission’s proposal to lower the level of protection for health and the environment and does not align with the objectives of the simplification omnibus. Sweden considers that 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, in line with Article 20(2).
(32) Article 49 is replaced by the following:		
‘*Article 49* **Placing on the market of treated seeds and plant reproductive material**		
1. The treatment of seeds and plant reproductive material with plant protection products as well as the sowing of the treated seeds and plant reproductive material constitutes a use of a plant protection product.	Placing on the market of treated seeds and plant reproductive material 1. The treatment of seeds and plant reproductive material with plant protection products ~~as well as the sowing of the treated seeds and plant reproductive material~~ constitutes a use of a plant protection product."	SE: Defining the sowing of treated seeds and the planting of treated plant reproductive material as the use of a plant protection product leads to an excessive new administrative burden for authorities, users and control bodies. The proposed provision is not in line with the aim of the Omnibus proposal. SE refers to its comments under Article 28(2). In our view, treated seeds is a treated article. An exception from the requirement of a product

Commission proposal	Drafting suggestions	Comments
		authorisation is therefore not needed. If there is a need, treated seeds and other treated articles could instead be regulated elsewhere in the Regulation. Such provisions should be considered in another context. SE notes that a consequence of the Commission proposing to define sowing of treated seed as a use of a plant protection product would imply that treated seed must be labelled in accordance with the CLP Regulation and the labelling Regulation for plant protection products, including national language requirements.
2. Placing on the market and use of seeds and plant reproductive material treated with a plant protection product which is not authorised in any Member State is prohibited.		
3. Member States can only prohibit the placing on the market or the use of seeds and 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		

Commission proposal	Drafting suggestions	Comments
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.		
6. Without prejudice to other Union legislation concerning the labelling of seeds and plant reproductive material, the label and documents accompanying the treated seeds and plant reproductive material shall include the name of the plant protection product with which they were treated, its authorisation number and the Member State which authorised it, the name(s) of the active substance(s) in that product, standard phrases for safety precautions as provided for in Regulation (EC) No 1272/2008 and, where applicable, risk mitigation measures set out in the authorisation for that product.		
7. Machinery used to sow treated seeds shall not be considered pesticide application equipment in the context of Article 8 of Directive 2009/128/EC.’;		
(33) Article 51 is amended as follows:		SE: Sweden supports the proposal, as it generally does not change how we have interpreted the rules to date. Concerning minor uses and mutual recognition, we have previously interpreted the

Commission proposal	Drafting suggestions	Comments
		rules to mean that the use in Sweden should be minor, but it does not need to be minor in the reference country; this has now been clarified in the proposal. Applicants who are not holders of the product authorisation have previously found it difficult to submit risk assessment data with their applications due to lack of access. The proposed changes make the process easier for applicants without significantly increasing the authorities' workload.
(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)(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 of residues and where necessary on the risk assessment as regards the operators, workers and bystanders.'		

Commission proposal	Drafting suggestions	Comments
(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		

Commission proposal	Drafting suggestions	Comments
		SE: Sweden welcomes the idea of EU-wide data protection for studies submitted for substance approval. However, it would be more practical for Member States and other stakeholders if the data protection of a study applied from the moment the substance is approved or renewed, rather than from its first use in a product authorisation, as it may be difficult to determine when a study was first used within the EU. Regarding product studies, submitted as part of product authorisations, the current system—where studies receive protection in a Member State once they have been used there—provides clarity about whether a study is protected. Under the proposed changes, it could be challenging to determine the first use of a study in any Member State, which would likely require the creation of a relevant EU-register.
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:		

Commission proposal	Drafting suggestions	Comments
(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		

Commission proposal	Drafting suggestions	Comments
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.		
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.		SE: Extending data protection as outlined in point 7 would be difficult, as it would involve altering the decision of another Member State, even though it concerns an EU-harmonised standard concerning data protection.
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		

Commission proposal	Drafting suggestions	Comments
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 Article 43 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 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, except for plant	‘1. Producers, suppliers, distributors, importers, and exporters of plant protection products shall keep records of the plant protection products they produce, import, export, store or place on the market for at least 5 years. Professional users of plant protection products shall, ~~except for plant~~	SE: Sweden considers that the Comissions proposal would significantly hinder enforecment of correct use. To evaluate the outcome of the stated Vision of the Commission to facilitate for biocontrol agents to reach the market will be facilitated by also keeping

Commission proposal	Drafting suggestions	Comments
protection products containing as active substances only biocontrol substances, for at least 3 years, keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used.	~~protection products containing as active substances only biocontrol substances,~~ for at least 3 years, keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used.	records of use of biocontrol substances, and make the statistics related to reduction targets more reliable. Further it would simplify for users to document all uses of plant protection products instead of assess which substances are exempted. Insufficient documentation may weaken the basis for the implementation of integrated pest management under Directive 2009/128/EC, as a complete spray record is essential for evaluating the measures taken." It may also affect and lead to reduced possibilities for statistical data collection, including under SAIO ((EU) 2022/2379)
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		
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'.		

Commission proposal	Drafting suggestions	Comments
(36) Article 68 is deleted.		
Article 2		
Transitional provisions concerning Regulation (EC) No 1107/2009		
(1) Article 14(2) of Regulation (EC) No 1107/2009 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 of Regulation (EC) No 1107/2009 as it stood before being amended by 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 of Regulation (EC) No 1107/2009 as amended by 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		SE: There are references to “last sentence” and “previous sentence”. However, there is only one sentence in Article 59(3)?

Commission proposal	Drafting suggestions	Comments
cover the Member States referred to in the previous sentence.		
(3) Article 23a (6) of Regulation (EC) No 1107/2009 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.		
Article 3		
Amendments to Regulation (EC) No 396/2005		
Regulation (EC) No 396/2005 is amended as follows:		
(1) Article 3(2) is amended as follows:		
(a) point (a) is replaced by the following:		
'(a) good agricultural practice' (GAP) means the recommended, authorised or registered safe use, either in the Union or a third country, of plant protection products under actual conditions at any stage of production, storage, transport, distribution and processing of food and feed. It also implies the application, in conformity with Regulation (EC) 1107/2009 and Directive 2009/128/EC, of the		

Commission proposal	Drafting suggestions	Comments
principles of integrated pest control in a given climate zone, as well as using the minimum quantity of pesticides and setting MRLs/temporary MRLs at the lowest level which allows the desired effect to be obtained. ;		
(b) point (f) is replaced by the following:		
'(f) 'limit of quantification' (LOQ) means the validated lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods;';		
(c) point (g) is deleted;		
(2) In Article 6, paragraph (4) is replaced by the following:		
'4. Applications for setting an MRL based on a GAP implemented in a third country shall be submitted to rapporteur Member States designated pursuant to Regulation (EC) No 1107/2009. If no such rapporteur has been designated, applications shall be made to Member States designated by the Commission in accordance with the procedure referred to in Article 45(2) of this Regulation at the request of the applicant. Such applications shall be made in accordance with Article 7 of this Regulation.';		

Commission proposal	Drafting suggestions	Comments
(3) In Article 10, paragraph (1), point (b) is replaced by the following:		
'(b) the anticipated LOQ for the pesticide/product combination;';		
(4) Article 14 is amended as follows:		
(a) In paragraph (2), a new subparagraph is added:		
– 'By way of derogation from 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 according to the latest available evaluation under Regulation (EC) No 1107/2009 or to a specific evaluation in accordance with Article 43 of 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 set in accordance with Article 18(1)(b) or Article 16 if considered appropriate in the light of the outcome of an impact assessment. ;		
(b) A new paragraph 2a is inserted:		

Commission proposal	Drafting suggestions	Comments
'2a. Where it is necessary in order to allow for the normal marketing, processing and consumption of products, the regulations setting or modifying MRLs provided for in Article 14 may establish transitional measures allowing for the placing or remaining on the market in the Union of products that, at the time of their placing on the market or at the time of their placing into storage after production, were compliant with the MRLs applicable or to which no MRL was applicable.		
The burden of proving when the products were placed on the market or placed into storage after production shall be borne by the food business operator.'		
(5) In Article 15, paragraph (1), point (c) is deleted.		
(6) Article 16 is replaced by the following:		
'*Article 16*		
Procedure for setting MRLs in certain circumstances		
1. The Commission may adopt a Regulation under Article 14(1) setting a MRL to be included in Annex III in the following circumstances:		

Commission proposal	Drafting suggestions	Comments
(a) in exceptional cases, in particular where pesticide residues may arise as a result of environmental or other contamination or from uses of plant protection products pursuant to Regulation (EC) No 1107/2009; or		
(b) where the products concerned constitute a minor component of the diet of consumers, and do not constitute a major part of the diet of relevant subgroups, and, where relevant, of animals; or		
(c) for honey; or		
(d) for herbal infusions; or		
(e) where essential uses of plant protection products have been identified by a Decision to delete an active substance from, or not to include an active substance in, Annex I to Directive 91/414/EEC; or		
(f) where new products, product groups and/or parts of products have been included in Annex I, and one or more Member States so request, in order to allow any scientific studies necessary for supporting an MRL to be undertaken and evaluated,		

Commission proposal	Drafting suggestions	Comments
provided that no unacceptable safety concerns for the consumer have been identified.		
2. The inclusion of MRLs as referred to in paragraph 1 shall be based on the opinion of the Authority, monitoring data and an assessment demonstrating that there are no unacceptable risks to consumers or animals.’;		
(7) In article 18, a new paragraph (1a) is inserted:		
‘1a. Where it is necessary in order to allow for the normal marketing, processing and consumption of products, the regulations setting or modifying MRLs provided for in Article 18 may establish appropriate transitional measures allowing for the placing or remaining on the market in the Union of products that, at the time of their placing on the market or at the time of their placing into storage after production, were compliant with the MRLs applicable or to which no MRLs was applicable.		
The burden of proving when the products were placed on the market or placed into storage after production shall be borne by the food business operator.;		
(8) in Article 31, paragraph (1), point(b) is replaced by the following:		

Commission proposal	Drafting suggestions	Comments
'(b) the LOQs applied in the national control programmes referred to in Article 30 and under the Community control programme referred to in Article 29;';		
(9) Article 43 is replaced by the following:		
'*Article 43*		
Scientific opinion of the Authority and review of MRLs		
1. The Commission or the Member States may request from the Authority a scientific opinion on any measure related to the assessment of risks under this Regulation. The Commission may specify the time limit within which such an opinion shall be provided.		
2. The Commission may review maximum residue levels established under this Regulation at any time in the light of new scientific and technical knowledge, taking into account the scientific opinion referred to in paragraph 1 where appropriate. '.		

Commission proposal	Drafting suggestions	Comments
Article 4 **Amendments to Regulation (EU) No 528/2012**		
Regulation (EU) No 528/2012 is amended as follows:		
(1) in Article 4, paragraph 1 is replaced by the following:		
'1. An active substance shall be approved if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in Article 19(1), point (b), taking into account the factors set out in Article 19(2) and (5).		
Approvals shall be for an unlimited time except for active substances that are identified as candidates for substitution in accordance with Article 10 or where the conditions of approval, for duly justified reasons, specify the expiry date of the approval in accordance with paragraph 3 of this Article. An active substance that falls under Article 5 may only be approved for an initial period not exceeding five years.';		SE: Sweden maintains a scrutiny reservation on article 4.
(2) in Article 4, paragraph 3, point (h) is replaced by the following:		

Commission proposal	Drafting suggestions	Comments
'(h) the date of approval and, when appropriate, the expiry date of the approval of the active substance.' ;		
(3) in Article 9, paragraph (1), point (a) is replaced by the following:		
'(a) adopt an implementing Regulation providing that an active substance is approved, and under which conditions, including the date of approval and, when appropriate, date of expiry of the approval; or';		
(4) In Article 10, paragraph (4) is replaced by the following:		
'The approval of an active substance that is considered as a candidate for substitution and each renewal shall be for a period not exceeding seven years.';		
(5) In Article 12, paragraph (3) is replaced by the following:		
'3. The renewal of an approval of an active substance shall be for an unlimited time for all product-types to which the approval applies, unless the active substance is identified as a candidate for substitution in accordance with Article 10 or a		SE: Sweden remains a scrutiny reservation on Article 12.

Commission proposal	Drafting suggestions	Comments
shorter period is specified in the implementing act adopted in accordance with Article 14(4), point (a), renewing such an approval.’;		
(6) in Article 13, paragraph 1 is replaced by the following:		
‘1. Applicants wishing to seek renewal of the approval of an active substance, which is subject to a specified expiry date for one or more product-types, shall submit an application to the Agency at least 550 days before the expiry of the approval. Where there are different expiry dates for different product-types, the application shall be submitted at least 550 days before the earliest expiry date.’;		
(7) a new Article 14a is inserted:		
‘*Article 14a*		
Renewal of an active substance with unlimited approval		
1. The Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 82(3) identifying active substances with unlimited approval for which a renewal procedure shall be conducted. The implementing acts shall list the active substances and product-types concerned, and set the expiry		SE: Sweden maintains a scrutiny reservation on Article 14a.

Commission proposal	Drafting suggestions	Comments
date of their current approvals that allows for an evaluation of the applications and the adoption of a decision on the renewal of approval.		
Article 13 and Article 14 apply *mutatis mutandis* for the submission, acceptance and evaluation of the applications.		
2. The identification of the active substances concerned shall take into account, among others, relevant new or updated data requirements or guidance documents, indications of safety concerns for human or animal health or the environment, new scientific or technical knowledge and available monitoring data, and may take into account requests from Member States.’;		
(8) a new Article 15a is inserted:		
‘*Article 15a*		
Approval periods of active substances approved by *[OP, please insert the date: date of the entry into force of this Regulation]*		
For all active substances approved under Regulation (EU) No 528/2012 at the latest on *[OP, please insert the date: date of the entry into force of this Regulation]* for one or more product-types, approvals shall be deemed unlimited in time for the concerned product-types, except for:		SE: Sweden maintains a scrutiny reservation on Article 15a.

Commission proposal	Drafting suggestions	Comments
(a) active substances identified as meeting the criteria set out in Article 5(1) or Article 10;		
(b) active substances for which an application for renewal was submitted by the deadline set out in Article 13(1) by *[OP, please insert the date: date of the entry into force of this Regulation]*;		
(c) active substances for which no application for renewal was submitted by the deadline set out in Article 13(1) by *[OP, please insert the date: date of the entry into force of this Regulation].';*		
(9) In Article 44, paragraph (5) is replaced by the following:		
'5. Upon receipt of the opinion of the Agency, the Commission shall adopt either an implementing act granting the Union authorisation of the biocidal product or an implementing act stating that the Union authorisation of the biocidal product has not been granted. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).		Sweden supports this proposal.
Summaries of Commission decisions shall be published in the Official Journal of the European		Sweden supports this proposal

Commission proposal	Drafting suggestions	Comments
Union, indicating the decision number, the nature of the decision, the name of the biocidal product, the active substances contained in the biocidal product, the product-types, the authorisation number, the authorisation holder, and the expiry date of the authorisation.		
The Commission shall, at the request of a Member State, decide to adjust certain conditions of a Union authorisation specifically for the territory of that Member State or decide that a Union authorisation shall not apply in the territory of that Member State, provided that such a request can be justified on one or more of the grounds referred to in Article 37(1).';		Sweden support this proposal.
(10) In Article 46, paragraph (4), the first subparagraph is replaced by the following:		
'Upon receipt of the opinion of the Agency, the Commission shall adopt an implementing act renewing the Union authorisation or refusing to renew the Union authorisation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).'.		Sweden support this proposal.
[...] *N.B. Articles 5-12 (amendments to Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) 1831/2003, (EC) No 852/2004, (EC) No 853/2004,*		

Commission proposal	Drafting suggestions	Comments
(EC) No 1099/2009, (EU) 2017/625) are covered by the consultation on 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		