Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 852/2004, (EC) No 853/2004, (EC) No 396/2005, (EC) No 1099/2009, (EC) No 1107/2009, (EU) No 528/2012, (EU) 2017/625 as regards the simplification and strengthening of food and feed safety requirements

2025/0410

Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Regulations

(EC) No 999/2001

- of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

(EC) No 1829/2003

- of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance)

(EC) No 1831/2003

- of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (Text with EEA relevance)

(EC) No 852/2004

- of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

(EC) No 853/2004

- of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin

(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 Text with EEA relevance.
    - of 15 July 1991 concerning the placing of plant protection products on the market

(EC) No 1099/200

- of 24 September 2009 on the protection of animals at the time of killing

(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
    - 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances
    - 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market

(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 Text with EEA relevance

(EU) 2017/625

- of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations [...] (Official Controls Regulation) (Text with EEA relevance)

Council topics division

Pesticide

Animal and food

Biocides

RECITALS

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
	Recital 8 The risk assessment of biocontrol substances requires specific technical knowledge, and some Member States do not have enough experts specialised in this type of assessment. As a result, some applicants for approval of biocontrol substances face difficulties in finding a rapporteur Member State. In order to increase capacity for the assessment of new biocontrol substances, it should be possible for the European Food Safety Authority ("the Authority") to assume the role of the rapporteur Member State for the assessment of applications for approval and the Authority's resources should be increased accordingly. The Authority should put in place appropriate safeguards to ensure independence of the subsequent peer review and to avoid any possible conflict of interests for the experts involved at the different stages of the assessment.	**Recital 8** The risk assessment of biocontrol substances requires specific technical knowledge, and some Member States do not have enough experts specialised in this type of assessment. As a result, some applicants for approval of biocontrol substances face difficulties in finding a rapporteur Member State**,** ***leading to procedural delays and constraints in the assessment process***. 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.	
		Recital 11 (New) ***In order to facilitate the effective uptake of biocontrols and ensure that farmers across the Union can access and deploy such solutions under comparable conditions, it is appropriate to provide for the possibility of targeted financial support under the Common Agricultural Policy. Such support should accompany the transition towards more sustainable crop protection systems and contribute to a level playing field in the internal market, while ensuring coherence with the objectives of the Common Agricultural Policy.***	
		Recital 23a ***(23a) Nursery production and the floriculture sector represent a fundamental pillar of the Union's agricultural economy, ensuring the supply of healthy, high-quality plant reproductive material essential for food security, sustainable agricultural production, and urban biodiversity. The technical specificities of nursery production - including high planting density, the smaller size of plant specimens, and cultivation in***	

		protected environments or containers - differ substantially from open-field conditions. These differences often render standard dosage instructions reported in current authorizations technically inaccurate or inapplicable for nursery settings.	
		Recital 23b ***(23b) The implementation of digital record-keeping systems interconnected with official farm files should be consistent with label authorizations and actual field use. Without such consistency, nursery growers face a legal impossibility to protect their crops from phytosanitary threats, even when chemically suitable active substances are available on the market. It is therefore important to ensure that nursery production is recognized as a distinct cultural category. Authorization procedures and the labelling of plant protection products should account for its unique biological, technical, and economic characteristics to ensure the sector's continued viability and competitiveness.***	

		Recital 27a ***(27a) To ensure a level playing field between Union producers and those in third countries, and to uphold the Union's high environmental and health objectives, it is necessary to further develop the principle of reciprocity in production standards. The Commission shall, following the completion of the ongoing impact assessment launched in November 2025, evaluate the necessity of establishing a formal definition and framework for reciprocity. This framework should ensure that imported products are subject to requirements equivalent to those applicable in the Union, particularly regarding the use of pesticides with global environmental impacts, such as those affecting biodiversity and the climate, in accordance with the Union's international obligations.***	
	Recital 37 Therefore, to ensure the good functioning of the internal market and provide legal certainty to food and feed business operators, food and feed products obtained using a GMM as production strain and from which the GMM has been removed should not fall within the scope of	***Recital 37*** *Therefore, to ensure the good functioning of the internal market,* ~~***and***~~ *provide legal certainty to food and feed business operators* ***and to support innovation and technological progress in the agri-food and biotechnology sectors,*** *food and feed products*	

	Regulation (EC) No 1829/2003 even if residues of the GMM are present in the food or feed, provided that they are limited to non-viable cells, that the presence thereof is minimized through reasonable attempts to remove them and have no technological effect on the final food or feed. In particular, in order to ensure that reasonable attempts to remove residues have been made, it should be required that they have been carried out in accordance with good manufacturing practices as those used in similar food and feed products to minimize the presence of residues.	*obtained using a GMM as production strain and from which the GMM has been removed should not fall within the scope of Regulation (EC) No 1829/2003 even if residues of the GMM are present in the food or feed, provided that they are limited to non-viable cells, that the presence thereof is minimized through reasonable attempts to remove them and have no technological effect on the final food or feed. In particular, in order to ensure that reasonable attempts to remove residues have been made, it should be required that they have been carried out in accordance with good manufacturing practices as those used in similar food and feed products to minimize the presence of residues.*	
		New ***Agricultural land plays a fundamental role in ensuring the production of food, feed and raw materials and is essential for the Union's food security, competitiveness and strategic autonomy. Plant protection products contribute to safeguarding agricultural production and should support the sustainable use of agricultural land for these purposes.***	

		New ***In exceptional circumstances, the non-approval or non-renewal of an active substance may have disproportionate consequences for agricultural viability, food production or food security compared to the risks arising from its use. This may occur where endemic soil pests cause recurrent crop losses, effective alternatives are unavailable and seed treatment remains the only technically viable preventive measure. In such cases, approval or renewal should be possible, provided that appropriate risk mitigation measures are applied.***	
		The efficacy and risk assessment of active substances should adequately reflect the diversity of agronomic, climatic and environmental conditions across the Union. Where an intended use concerns biogeographical regions with specific pedoclimatic conditions not covered by the rapporteur Member State, relevant Member States, competent authorities and research institutes should be consulted to ensure that regional specificities, scientific expertise and available monitoring data are duly taken into account and that any data gaps are identified before the completion of	

		the peer review.	
		New ***Minor crops and minor uses often face limited availability of authorised plant protection products due to the high costs and administrative burden associated with generating the data required for authorisation. To improve the availability of plant protection solutions for those crops and uses, those costs and administrative requirements should be minimised, and the Commission should support the generation of the necessary data and authorisations of the such plant protection products for minor uses.***	

Article 1

Amendments to Regulation (EC) No 1107/2009

1) Article 2 – Scope

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
		Par. 1 (a) new ***Article 4(7) of Regulation (EC) No 1107/2009 as amended by [OP: please insert reference of this regulation] shall also apply to active substances for which an application for renewal of approval has been submitted before [date of entry into force of this Regulation].***	
Par 1 (b) (b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient;	(b) 'disrupting life processes of plants, such as substances regulating their growth, other than as a nutrient or a plant biostimulant'		
Par. 2 2. This Regulation shall apply to substances, including micro-organisms having general or	*Paragraph 2 is replaced by the following:* '2. This Regulation shall apply to substances, including biocontrol substances having general or specific		

specific action against harmful organisms or on plants, parts of plants or plant products, referred to as 'active substances'.	action against harmful organisms or on plants, parts of plants or plant products, referred to as 'active substances.';		

2) Article 3 - Definitions (17) (34) (35) (36)

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Point 17 17. 'zone' means a group of Member States as defined in Annex I. For the purpose of use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment the zone means all zones defined in Annex I;	*Point 17 is replaced by the following:* '17. ´zone´ means a group of Member States as defined in Annex I. For the purpose of use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment, for uses that are solely and explicitly needed in order to prevent the entry into, and spread within, the Union, of pests listed in accordance with Articles 5(2), 30(1), 32(3), 37(2) of Regulation (EU) 2016/2031 and for plant protection products containing as active substances only biocontrol or low-risk active substances, the zone means all zones defined in Annex I.';	*17. ´zone´ means a group of Member States as defined in Annex I.* *For the purpose of use in greenhouses, **for all minor crops**, 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 **for plant protection products to be used for application by such unmanned aircraft systems in accordance with Directive 2009/128/EC** 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.	
Point 34	*Point 34 is replaced by the following:* '34. 'plant biostimulant' means a product having at least one of the following actions: (1) stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere: (a) nutrient use efficiency; (b) quality traits; (c) availability of confined nutrients in soil or rhizosphere; (2) stimulating life processes of crops to improve their tolerance to abiotic stress. Substances disrupting life processes of crops which are not fulfilling the definition of plant biostimulants are active substances covered by this Regulation.';		
Point 35	*The following point 35 is added:*	*35. 'biocontrol substance' means:*	

	'35. 'biocontrol substance' means: (a) micro-organisms, (b) 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.';	*a) micro-organisms,* *b) 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.';*	
Point 36	*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.';		
Point 36 new		***New point 36 a is added:*** ***'nursery production': means the activity of multiplication, grafting, and rearing of plants, including plant reproductive material, ornamental plants, cut flowers, young fruit trees, and vegetable seedlings, whether in open fields or under protected conditions. This***	

		activity is characterized by a high planting density per unit area and by plant biometric and phenological parameters that substantially differ from those of crops intended for food, fruit, or industrial production in their adult stage.	

3) Article 4 - Approval for active substance

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Par. 1 **1.** An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the		*1. An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge,* ***including a risk assessment based on the availability of risk management measures with particular regard to application techniques****, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3.*	

requirements provided for in paragraphs 2 and 3.			
Par. 3 **3.** A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements: (a) it shall be sufficiently effective;		*3. A plant protection product, following an application in accordance with good plant protection practices and taking into account realistic conditions of use,* ***including a risk assessment based on the availability of risk management measures with particular regard to application techniques,*** *shall meet the following requirements:* ***a) shall ensure a sufficiently high level of efficacy;***	
Par 4.7. **4.7.** By way of derogation from paragraph 1, where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious	4.7. 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 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	*4.7. 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,* ***within 3 month of EFSA conclusion****, an active substance is necessary to* ***effectively*** *control a serious danger to plant health, or plant production which cannot be contained by other reasonable means including non-chemical methods****.***	

danger but not exceeding five years even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.	years, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005. The derogation provided for in the first subparagraph shall not apply to active substances which are or have to be classified in accordance with Regulation (EC) No 1272/2008, as mutagenic category 1A or 1B, carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A, or persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), or that are a persistent organic pollutant (POP) according to the criteria set out in point 3.7.1 of Annex II. Member States may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control the serious danger to plant health or plant production in	***The application referred to in the first subparagraph shall be submitted during the approval process by the applicant for approval and/or by official or scientific bodies involved in agricultural activities and/or by professional agricultural organizations*** ***Decisions on derogations should take on the base of a socio-economic and agro-economic assessment including efficacy, impact of pests on farmers yield and risks for cross-resistance.*** *Such active substance may be approved for a limited period* ***ensuring that those essential uses are not lost where no viable options exist.*** *The use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005. The 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)*	

	their territory identified pursuant to the first subparagraph.’;	*No 1272/2008, as mutagenic category 1A or 1B, carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A, or persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), or that are a persistent organic pollutant (POP) according to the criteria set out in point 3.7.1 of Annex II. Member States may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control the serious danger to plant health or plant production in their territory identified pursuant to the first subparagraph;*	

4) Article 5 - First approval

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
First approval shall be for a period not exceeding 10 years.	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 (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) Article 7 – Application

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Par. 1 1. An application for the approval of an active substance or for an amendment to the conditions of an approval 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 Article 8(1) and (2) or	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		

a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in Article 4.	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. 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.’;		
		Par. 1 (a) new ***The evaluation of the application for the approval of an active substance shall be completed within a period not exceeding 18 months from the date of submission of a complete dossier.***	

6) Article 11 - Draft assessment report

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
	The following paragraph 1a is added: 1a. The rapporteur Member State shall give priority to the assessment of applications for approval of biocontrol substances.’;	*1a. The rapporteur Member State shall give priority to the assessment of applications for approval of biocontrol substances.* ***Where the intended use of an active substance concerns biogeographical regions with specific pedoclimatic conditions not covered by the rapporteur Member State, the rapporteur Member State shall coordinate with the Member States whose territory includes those***	

		biogeographical regions to ensure that: ***(a) efficacy assessments reflect the full range of conditions under which the product is intended to be used within the Union;*** ***(b) region-specific data gaps are identified and addressed before completion of the peer review;*** ***(c) competent authorities and research institutes from Member States hosting unique biogeographical regions are consulted as part of the assessment procedure.***	

7) Article 13 - Approval regulation

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
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.	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) Head of subsection 3

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Renewal and review	**Renewal, reassessment and review**		

9) Article 14 - Renewal of approval

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Par. 1 1. On application the approval of an active substance 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.	**Par. 1** 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 the approval shall be for a period not exceeding 15 years. The renewal of approval of active substances covered by Article 4(7) shall be for a period not exceeding five years.	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 (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 - Work programme for renewal of approval of active substance with unlimited approval periods

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Par. 1 The Commission may establish a work programme grouping together similar active substances setting priorities on the basis of safety concerns for human and animal health or the environment	**Par. 1** 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	***Par. 1*** *The Commission **may** periodically after consulting the Authority, adopt implementing acts in accordance with the procedure referred to in*	

and taking into account, as far as possible, the need for an effective control and resistance management of target pest. The programme may require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a period provided for in the programme. The programme shall include the following: (a) the procedures concerning the submission and assessment of applications for renewal of approvals; (b) the necessary data to be submitted, including measures to minimise animal testing, in particular the use of non-animal test methods and intelligent testing strategies; (c) the periods for submission of such data; (d) rules on the submission of new information; (e) period for assessment and decision making; (f) the allocation of evaluation of active substances to Member States, taking into account a balance in the responsibilities and work to be done	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. 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.	*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* ***broad-ranging*** *indications of* ***significant*** *safety concerns for human or animal health or the environment, new scientific or technical knowledge and available monitoring data and may take into account requests from Member States.* *The Commission shall adopt an implementing act identifying all relevant active substances, as referred to in the first subparagraph, at the latest 3 years after amendments to the approval criteria set out in Annex II relevant for these active substances, or when updated data requirements or guidance documents relevant for these active substances become applicable* ***in case of indication of safety concerns.***	

among Member States acting as rapporteurs.			
	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 renewal of the approval of the active substances concerned.	***(ca) new: specify which guidance documents are to be considered by applicants at the time of submission; and***	

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

11) New Article 18a - Work programme for targeted reassessment of active substances

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
	Par. 1 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).		
	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.	*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* ***exclusively*** *be used; and*	
	3. Where the Commission concludes that compliance with the relevant approval criteria covered by the targeted reassessment is demonstrated, it shall adopt an implementing act, confirming the approval, where applicable with conditions and restrictions in accordance with Article		

	6, in accordance with the procedure referred to in Article 79(3).		
	4. Where the information referred to in paragraph 2 point (d) has not been provided within the time period established, the Commission shall adopt an implementing act withdrawing the approval in accordance with the procedure referred to in Article 79(3). Where the Commission concludes that the approval criteria covered by the targeted reassessment are no longer satisfied, it shall adopt an implementing act withdrawing the approval in accordance with the procedure referred to in Article 79(3). In case the derogation set out in Article 4(7) applies, that implementing act may amend the approval.		
	5. Articles 13(4), 17 and 20(2) shall apply.’;		

12) Article 19 - Implementing measures

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification

A Regulation, adopted in accordance with the regulatory procedure referred to in Article 79(3), shall set out the provisions necessary for the implementation of the renewal procedure, including, where relevant, the implementation of a work programme, as provided for in Article 18.	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 the targeted reassessment procedure, as provided for in this Subsection 3.'		

13) Article 20 - Renewal regulation

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Par. 2 2. Where the reasons for not renewing the approval do not concern the protection of health or the environment, the Regulation referred to in paragraph 1 shall provide for a grace period not exceeding six 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. The grace period for the sale and distribution shall take	**Par. 2** 2. The Regulation referred to in paragraph 1 shall provide for a maximum grace period that the Member States may set when withdrawing or amending authorisations for plant protection products as a result of that Regulation. That maximum grace period shall normally not exceed 6 months for the sale and distribution, and in addition a maximum of one year for the disposal, storage, and use of existing stocks of	*'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 two years 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.*	

into account the normal period of use of the plant protection product but the total grace period shall not exceed 18 months. In the case of a withdrawal of the approval or if the approval is not renewed because of the immediate concerns for human health or animal health or the environment, the plant protection products concerned shall be withdrawn from the market immediately.	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 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.’;*	

14) Article 22 - Low-risk active substances

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Par. 1 and 2 1. An active substance complying with the criteria provided for in Article 4	**Par. 1 and 2** ‘1. An active substance complying with the criteria provided for in		

shall be approved for a period not exceeding 15 years by way of derogation from Article 5, where it is considered a low-risk active substance and where it may be expected that plant protection products containing that substance will pose only a low risk to human and animal health and the environment as provided for in Article 47(1). 2. Articles 4 and 6 to 21 and point 5 of Annex II shall apply. Low-risk active substances shall be listed separately in the Regulation referred to in Article 13(4).	Article 4 and in point 5 of Annex II shall be approved as a low-risk active substance. 2. Articles 4 to 21 shall apply. Low-risk active substances shall be listed separately in the Regulation referred to in Article 13(4).’;		

15) Article 23 - Approval criteria for basis substances

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Par. 2 2. By way of derogation from Article 4, a basic substance shall be approved where any relevant evaluations, carried out in accordance with other Community legislation regulating the use of that substance for purposes	**Par. 2** 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	**Par. 2 point c)** ~~*(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*~~	

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. 3. 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) any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other Community legislation regulating the use of the substance; and (b) other relevant information on its possible effects on human or animal health or the environment.	classification of the substance in accordance with Regulation (EC) No 1272/2008 does not apply to the product in which it is approved for use; (b) the basic substance 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 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.’;	~~*active substance is under assessment at that moment;*~~ ***(c) If a registered active substance qualifies by definition as a basic substance, it shall be included in the catalogue of basic substances and simultaneously removed from the list of active substances.***	

16.1) Article 24 – Candidates for substitution (NOT IN OMNIBUS):

		1. An active substance complying with the criteria provided for in Article 4 shall be approved, for a period not exceeding ~~***seven***~~ ***fifteen*** years, as a candidate for substitution if it meets one or more of the additional criteria laid down in point 4 of Annex II. By way of derogation from Article 14(2), the approval may be renewed once or more for periods not exceeding ~~***seven***~~ ***fifteen*** years ***on the basis of a socio-economic and agro-economic assessment including for instance efficacy, impact of pests on farmers yield, and risks for cross-resistance.*** 1. Without prejudice to paragraph 1, Articles 4 to 21 shall apply. Candidates for substitution shall be listed separately in the Regulation referred to in Article 13(4). 2. ***Before withdrawing or not renewing the approval of an active substance approved as a candidate for substitution, the Commission shall assess whether alternative substances***	

		or methods are available that provide an equivalent level of effectiveness and are economically viable for farmers. Such an assessment shall take into account agronomic needs, the availability of alternatives across different climatic zones, and the potential impacts on agricultural production.	

16) New Article 23a - Approval procedure and labelling of basis substances

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
	Article 23a 1. By way of derogation from Article 7, an application for the approval of a basic substance shall be submitted by a Member State or by any interested party to the Commission. The application shall be accompanied by the following information: (a) intended uses and proposed conditions of use of the basic substance;		

	(b) any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other Union legislation regulating the use(s) of the substance; and (c) other relevant information on its possible effects on human or animal health or the environment. 2. The Commission shall ask the Authority for an opinion or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within 3 months of the date of the request. 3. Articles 6 and 13 shall apply. Basic substances shall be listed separately in the Regulation referred to in Article 13(4). 4. The approval shall cover all approved uses of the basic substances and any product containing it as specified under Article 23a without being limited by the uses applied for. The approval shall be for an unlimited period and Articles 59 to 62 shall not apply. 5. Where a substance approved as a basic substance is subsequently also approved as an active substance that is not a basic substance, that approval		

	shall not affect the existing approval as a basic substance, as well as the placing on the market and use as basic substance or product as refer to in Article 23(1). 6. Any applicant may request an extension of the approved uses of a basic substance. Paragraphs 1 to 4 apply. Where justified in the light of the outcome of the evaluation, the Commission shall update the review report for the basic substance, including a reference to the applicable review report in the approval regulation. 7. The Commission may review the approval of a basic substance at any time. It may take into account the request of a Member State to review the approval. Where the Commission considers that there are indications that the substance no longer satisfies the criteria provided for in paragraph 2 of Article 23 it shall inform the Member States, the Authority and the interested party, setting a period for their comments to be submitted. The Commission shall ask the Authority for an opinion, or for scientific or		

	technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within three months of the date of the request. Where the Commission concludes that the criteria referred to in paragraph 1 are no longer satisfied, a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3). 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. 9. Detailed rules for the implementation of this Article may be established in accordance with the procedure referred to in Article 79(3).';		

17) New Article 27a - Approval periods of already granted approval

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
	Par. 1	**Par. 1 point d)**	

	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: (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]*.	~~*(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].*~~	

18) Article 28 - Authorisation for placing on the market and use

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification

Par. 2 2. By way of derogation from paragraph 1, no authorisation shall be required in the following cases: (a) use of products containing exclusively one or more basic substances;	**Par. 2** 2. By way of derogation from paragraph 1, no authorisation shall be required in the following cases: ‘(a) placing on the market and use of basic substances or products referred to in Article 23(1).’; ‘(f) (*new)* 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.’;	***f) treatment of seeds****, placing on the market and use of treated seeds and other treated plant reproductive material with plant protection products authorised for that use in at least one Member State.* ***g new) The use of products for treating seeds intended exclusively for export to third countries, in accordance with the legislation of the destination country, where the protection of human health in seed treatment facilities is ensured through clearly defined and appropriate risk-mitigation measures for workers and bystanders, consistent with internationally recognised principles and relevant OECD guidance.***	

18 a) Article 29 - Requirements for the authorisation for placing on the market (NOT IN OMNIBUS)

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification

Par. 3		***Par. 3*** *Compliance with the requirements set out in point (b) and points (e) to (h) of paragraph 1 shall be established by official or officially recognised tests and analyses carried out under agricultural, plant health and environmental conditions relevant to the use of the plant protection product in question and representative of the conditions prevailing in the zone where the product is intended to be used,* ***including a risk assessment based on the availability of risk management measures with particular regard to application techniques.*** ***Member States shall take into account all available risk mitigation measures when assessing whether the requirements are met.*** ***Where the intended area of use of a plant protection product includes biogeographical regions with specific pedoclimatic conditions not represented in the tests conducted by***	

		the rapporteur Member State, supplementary efficacy and risk data collected under the conditions of those regions shall be required as part of the authorisation dossier. ***Such supplementary data shall be taken into account in the authorisation decision and in any mutual recognition procedure under Article 40.*** ***This requirement applies in particular to biogeographical regions present in only one Member State of the Union, where specific pedoclimatic stress conditions — including elevated temperatures, drought periods or endemic soil pest pressure — may significantly affect product performance and efficacy compared to the conditions under which the standard tests were conducted.***	

19) Article 30 - Provisional authorisation

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification

Provisional authorisations 1. By way of derogation from Article 29(1)(a), Member States may authorise for a provisional period not exceeding 3 years, the placing on the market of plant protection products containing an active substance not yet approved, provided that: (a) the decision on approval could not be finalised within a period of 30 months from the date of admissibility of the application, extended by any additional period set in accordance with Article 9(2), Article 11(3) or Article 12(2) or (3); and (b) pursuant to Article 9 the dossier on the active substance is admissible in relation to the proposed uses; and (c) the Member State concludes that the active substance can satisfy the requirements of Article 4(2) and (3) and that the plant protection product may be expected to satisfy the	**Provisional authorisations for plant protection products containing biocontrol active substances** 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); (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	***Provisional authorisations for plant protection products containing biocontrol active substances*** *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);* ***The implementation of paragraph 1 shall not undermine the provisional authorisations for plant protection products***	

requirements of Article 29(1)(b) to (h); and (d) maximum residue levels have been established in accordance with Regulation (EC) No 396/2005.	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.	***containing an active substance not yet approved.***	

19 a) Article 31 - Contents of Authorisations

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Par. 4		***In Article 31(4), after point (i), the following point is added:*** ***i) a new*** ***where applicable, the specific conditions, application methods, and dosages for nursery production, ensuring that such parameters are proportionate to planting density and plant size, clearly distinguishing them from dosages for open-field crops.***	

20) Article 32 – Duration

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Duration 1. The period of authorisation shall be laid down in the authorisation. Without prejudice to Article 44, the duration of an authorisation shall be set for a period not exceeding 1 year from the date of expiry of the approval of the active substances, safeners and synergists contained in the plant protection product and thereafter for as long as the active substances, safeners and synergists contained in the plant protection product are approved. This period shall allow the examination as provided for in Article 43 to be carried out. 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	**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, (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. 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	**Duration** *1. The period of authorisation shall be laid down in the authorisation.* ***Authorisations shall be for an unlimited time if the plant protection product concerned contains only active substances, safeners, and synergists with unlimited approval period, and it has been assessed according to this Regulation considering the latest assessments underlying the approvals of the active substances, safeners, and synergists contained in the product.*** *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,*~~ *(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*	

candidates for substitution as provided for in Article 50.	candidates for substitution as provided for in Article 50.’;	*concerned* ***and thereafter for as long as the active substances, safeners and synergists contained in the plant protection product are approved.*** *This period shall allow the examination as provided for in Article 43 to be carried out.* ***Where no expiry date is set for an active substance (unlimited approval), the re-evaluation of the plant protection product should take place no later than one year after the re-evaluation of the active substance.***	

21) Article 33 - Application for authorization or amendment of an authorisation

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
(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, only one Member State shall be proposed, which evaluates the	‘(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	*(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*	

application taking account of all zones. In this case the applicant shall send the summary or complete dossier as referred to in Article 8 to other Member States on request;	into, and spread within, the Union, of pests listed in accordance with Articles 5(2), 30(1), 32(3) and 37(2) of Regulation (EU) 2016/2031 and for a plant protection product containing as active substances only biocontrol or low-risk active substances, only one Member State shall be proposed, which evaluates the application taking account of all zones. In this case the applicant shall send the summary or complete dossier as referred to in Article 8 to other Member States on request.'; 	*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* ***for plant protection products to be applied by such unmanned aircraft systems in accordance with Directive 2009/128/EC*** *and for a plant protection product containing as active substances only biocontrol or low-risk active substances, only one Member State shall be proposed, which evaluates the application taking account of all zones. In this case the applicant shall send the summary or complete dossier as referred to in Article 8 to other Member States on request.*	

22) Article 36 - Examination authorisation

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
'1. The Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and	'1. The Member State examining the application shall make an independent, objective and transparent assessment in the light of current	*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 application. It shall give all Member States in the same zone the opportunity to submit comments to be considered in the assessment. It shall apply the uniform principles for evaluation and authorisation of plant protection products, referred to in Article 29(6), to establish, as far as possible, whether the plant protection product meets the requirements provided for in Article 29 in the same zone, where used in accordance with Article 55, and under realistic conditions of use. The Member State examining the application shall make available its assessment to the other Member States within the same zone. The format of the assessment report shall be established in accordance with the advisory procedure referred to in Article 79(2).	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.’;	*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,* ***in particular on EFSA Conclusions and agreed List of Endpoints supporting the (renewal of) approval. When a Member State*** *considers that an update is necessary in the light of the current scientific and technical knowledge, the Member State shall request the Commission to act under Articles 18, 18a or 21.* ***However, such request will follow a separate procedure and shall not suspend, postpone or withdraw the examination of the application for authorization of the plant protection product.***	
		3. By way of derogation from paragraph 2 and subject to Community legislation,	

		~~***appropriate conditions may be imposed with respect***~~ ***Member States may take into account the available risk mitigation measures in order to apply specific conditions of use appropriate*** *to the requirements referred to in Article 31(3) and (4).* ~~***and other risk mitigation measures deriving from specific conditions of use.***~~ ~~***Where the concerns of a Member State relating to human or animal health or the environment cannot be controlled by the establishment of the national risk mitigation measures referred to in the first subparagraph, a Member State may refuse authorisation of the plant protection product in its territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment***~~*.* *That Member State shall immediately inform the applicant and the Commission of its*	

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

23) Article 37 - Period of examination

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
	‘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. 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.	*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.* *6. The Member State examining the application shall give, **where feasible,** priority to the processing of*	

	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.’;	*applications for plant protection products containing as active substances only biocontrol substances.*	

24) Article 40 - Mutual recognition

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
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 the comparable agricultural practices in another Member State under the mutual recognition procedure, provided for in this subsection, in the following cases:	1. The holder of an authorisation granted in accordance with Article 29 may apply for an authorisation for the same plant protection product, the same use and under comparable agricultural practices in another Member State under the mutual recognition procedure, provided for in this subsection, in the following cases: (a) the authorisation was granted by a Member State (reference Member	***1. When** an authorisation **is** granted **to an applicant by a Member State** in accordance with Article 29**, such** authorisation for the same plant protection product, the same use and under comparable agricultural practices **is automatically granted to all** Member State **of the same zone** under the mutual recognition procedure*	

(a) the authorisation was granted by a Member State (reference Member State) which belongs to the same zone; (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; (c) the authorisation was granted by a Member State for use in greenhouses, or as post-harvest treatment, or for treatment of empty rooms or containers used for storing plant or plant products, or for seed treatment, regardless of the zone to which the reference Member State belongs.	State) which belongs to the same zone and the authorised plant protection product is placed on the market in the reference Member State; (b) the authorisation was granted by a Member State (reference Member State) which belongs to a different zone provided that the authorisation for which the application was made is not used for the purpose of mutual recognition in another Member State within the same zone and the authorised plant protection product is placed on the market in the reference Member State; (c) the authorisation was granted by a Member State for use in greenhouses, as post-harvest treatment, for treatment of empty rooms or containers used for storing plant or plant products, for seed treatment, for uses that are solely and explicitly needed in order to apply the provisions of Regulation (EU) 2016/2031 or for plant protection products containing as active substances only biocontrol active substances regardless of the zone to which the reference Member State belongs and the authorised plant	***By way of derogation, automatic mutual recognition is also granted in the following cases:*** ~~*(a) the authorisation was granted by a Member State (reference Member State) which belongs to the same zone and the authorised plant protection product is placed on the market in the reference Member State*~~ ~~*(b) the authorisation was granted by a Member State (reference Member State) which belongs to a different zone provided that the authorisation for which the application was made is not used for the purpose of mutual recognition in another Member State within the same zone and the authorised plant protection product is placed on the market in the reference Member State;*~~ ~~c)~~ *(a) 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*	

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, with the consent of the authorisation holder, 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. In that case the applicant must demonstrate that the use of such a plant protection product is of general interest for the Member State of introduction. Where the authorisation holder refuses its consent, the competent authority of the Member	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.’;	*and explicitly needed in order to apply the provisions of Regulation (EU) 2016/2031 or for plant protection products containing as active substances only biocontrol 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.* *(c.a new) b)* ***in case of seed treatment, automatic mutual recognition will be granted if the plant protection product is authorised in at least one EU Member State for seed treatment in professional facilities.*** *2. Where a plant protection product is not authorised in a Member State because* ***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****, official or scientific bodies involved in agricultural activities or professional agricultural organisations may apply for an*	

State concerned may accept the application, on grounds of public interest.		*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 - Procedure

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1. The application shall be accompanied by the following: (a) a copy of the authorisation granted by the reference Member State as well as a translation of the authorisation into an official language of the Member State receiving the application; (b) a formal statement that the plant protection product is identical to that authorised by the reference Member State; (c) a complete or summary dossier as required in Article 33(3) when requested by the Member State;	1. The application shall be accompanied by the following: (a) a copy of the authorisation granted by the reference Member State as well as a translation of the authorisation into an official language of the Member State receiving the application; (b) a formal statement that the plant protection product is identical to that authorised by the reference Member State; (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. 2. The Member State to which an application under Article 40 is submitted shall decide on the application within 120 days. 3. 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.	(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. 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 - Renewal of authorisation

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
2. Within 3 months from the renewal of the approval of an active substance, safener or synergist contained in the plant protection product, the applicant shall submit the following information:	‘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:

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
(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.	(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.'; **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;'**		

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
5. Member States shall decide on the renewal of the authorisation of a plant protection product at the latest 12 months after the renewal of the approval of the active substance, safener or synergist contained therein.	5. 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;’;		

29) Article 44 - Withdrawal or amendment of an authorisation

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification

30) New Par. Article 44

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
	‘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.’;		

31) Article 46 - Grace period

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Where a Member State withdraws or amends an authorisation or does not renew it, it may grant a grace period for the disposal, storage, placing on the market and use of existing stocks. Where the reasons for withdrawal, amendment or non-renewal of the authorisation are not related to the protection of human and animal health or the environment, the grace period shall be limited and 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.	**Par. 1** 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) .	**Par. 1** *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).*	
	Par. 2 2. Where a Member State withdraws or amends an authorisation or does not renew it for other reasons than those referred to in paragraph 1, it may set a grace period that shall not exceed 6	***Par. 2*** *2. Where a Member State withdraws or amends an authorisation or does not renew it for other reasons than those referred to in paragraph 1, it may set a grace period that shall not*	

	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).’;	*exceed ~~6 months~~ **1 year** for the sale and the distribution and an additional maximum of ~~1~~ **2** year**s** for the disposal, storage, and use of existing stocks of the plant protection products concerned).*	
		Par. 2 a) new ***Products for agricultural input produced using such active substances before the entering into force of the new provisions can be marketed up to the end of the stocks.***	

32) Article 49 - Placing on the market of treated seeds

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1. Member States shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use in at least one Member State.	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.	**Par. 1** ***1. Treated seeds and plant reproductive material are not to be considered a plant protection product****. 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 ***precision application*** *use of a plant protection product.*	
	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.	**Par. 6** *6. Without prejudice to other Union legislation concerning the labelling of seeds and plant reproductive material, the label and documents accompanying the treated seeds and plant reproductive material shall include 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.*	

33) Article 51 - Extension of authorization for minor uses

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
2. Member States shall extend the authorisation provided that: (a) the intended use is minor in nature; (b) the conditions referred to in points (b), (d) and (e) of Article 4(3) and Article 29(1)(i) are satisfied; (c) the extension is in the public interest; and	'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.' '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.'; '7. The applicants referred to in paragraph 1 may also apply for	**Par. 2 point d)** ***d) The competent authorities shall support the bodies referred to in paragraph 1, other than the authorisation holder, in obtaining the documents and data necessary for the authorisation. In these cases, derogation should be allowed for the generation of data required for authorisation.*** **Par. 7** '7. The applicants referred to in paragraph 1 may also apply for	

3. Member States may take measures to facilitate or encourage the submission of applications to extend the authorisation of already authorised plant protection products to minor uses. 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) provided that a plant protection product concerned is authorised in that Member State. Member States shall authorise such uses in accordance with the provisions of Article 41 provided that those uses are also considered minor in the Member States of application. 9. By 14 December 2011, the Commission shall present a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal.	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).';.	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.' **Competent authorities shall support professional agricultural organisations and professional users for authorisation of minor uses;**	

33 a) <u>Article 53 - Emergency Situations in plant protections (NOT IN OMNIBUS)</u>

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1. By way of derogation from Article 28, in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means. The Member State concerned shall immediately inform the other Member States and the Commission of the measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety. 2. The Commission may ask the Authority for an opinion, or for scientific or technical assistance.		1. By way of derogation from Article 28, in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means. The Member State concerned shall immediately inform the other Member States and the Commission of the measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety. ***1 a. Following the notification by the Member State requesting authorisation for a limited and controlled emergency use, the Commission shall adopt a decision, according to the regulatory procedure referred to in Article 79(3), making the same derogation use***	

The Authority shall provide its opinion or the results of its work to the Commission within 1 month of the date of the request. 3. If necessary, a decision shall be taken, in accordance with the regulatory procedure referred to in Article 79(3), as to when and under what conditions the Member State: (a) may or may not extend the duration of the measure or repeat it; or (b) shall withdraw or amend its measure. 4. Paragraphs 1 to 3 shall not apply to plant protection products containing or composed of genetically modified organisms unless such release has been accepted in accordance with Directive 2001/18/EC.		***automatically applicable in all Member States belonging to the same zone as the Member State requesting the authorisation.*** 2. The Commission may 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 1 month of the date of the request. 3. If necessary, ***the Commission shall supplement the*** decision ***referred to in paragraph 1 a, based on the opinion of the Authority***, as to when and under what conditions the Member State***s of the same climatic zone***: (a) may or may not extend the duration of the measure or repeat it; (b) or shall withdraw or amend its measure. 4. Paragraphs 1 to 3 shall not apply to plant protection products containing or composed of genetically modified organisms unless such	

		release has been accepted in accordance with Directive 2001/18/EC.	
		4a new ***An extension of an authorisation granted by a Member State for a specific Crop / Pesticide / Pest or Disease combination, subject to the prior establishment by that Member State of appropriate risk management measures and application techniques, shall be immediately effective in all Member States within the same zone.***	

34) Article 59 - Data protection

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1. Test and study reports shall benefit from data protection under the conditions laid down in this Article. The protection shall apply 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)	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		

when they are submitted to a Member State by an applicant for authorisation under this Regulation, (the first applicant), provided that those test and study reports were: (a) necessary for the authorisation or an amendment of an 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. Where a report is protected, it may not be used by the Member State which received it for the benefit of other applicants for authorisation of plant protection products, safeners or synergists and adjuvants, except as provided in paragraph 2 of this Article, in Article 62 or in Article 80. The period of data protection is 10 years starting at the date of first authorisation in that Member State, except as provided in paragraph 2 of this Article or in Article 62. That period is extended to 13 years for plant protection products covered by Article 47. Those periods shall be extended by 3 months for each extension of	product as referred to in Article 8(2) when they are submitted to a Member State by an applicant for authorisation under this Regulation, ('the first applicant'), provided that those test and study reports were: (a) necessary for the authorisation or for an amendment of the authorisation in order to allow the use on another crop; and (b) certified as compliant with the principles of good laboratory practice or of good experimental practice. 3. Data protection shall be granted to the test and study reports referred to in paragraph 2 where the first applicant has requested it at the time of submitting the dossier and has provided to the Member State concerned, for each test or study report, the information referred to in point (f) of Article 8(1) and in point (d) of Article 33(3) as well as confirmation that a period of data protection under this Regulation has never been granted anywhere in the Union. 4. If the first applicant does not request data protection to be granted for a test or study report submitted for the first		

authorisation for minor uses as defined in Article 51(1), except where the extension of authorisation is based on extrapolation, if the applications for such authorisations are made by the authorisation holder at the latest 5 years after the date of the first authorisation in that Member State. The total period of data protection may in no case exceed 13 years. For plant protection products covered by Article 47 the total period of data protection may in no case exceed 15 years. The same data protection rules as for the first authorisation shall also apply to test and study reports submitted by third parties for the purpose of extension of authorisation for minor uses as referred to in Article 51(1). A study shall also be protected if it was necessary for the renewal or review of an authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply *mutatis mutandis*. 2. Paragraph 1 shall not apply: (a) to test and study reports for which the applicant has submitted a letter of access; or (b) where any period of data	time in a dossier under this Regulation, it shall not be data protected and it could be used for the benefit of any subsequent applicants. 5. Where a test or study report is protected, it may not be used by any Member State for the benefit of other applicants for authorisation of plant protection products, safeners or synergists and adjuvants, except as provided in Article 62 or in Article 80, or where: (a) the applicant has submitted a letter of access; or (b) any period of data protection granted for the test and study reports under this Regulation has expired. 6. The period of data protection shall be 10 years starting from the date of the authorisation in the first Member State granting an authorisation based on a dossier including the test or study report. That period is extended to 13 years for plant protection products covered by Article 47. 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		

protection granted for the test and study reports concerned in relation to another plant protection product has expired. 3. Data protection under paragraph 1 shall only be granted where the first applicant has claimed data protection for test and study reports concerning the active substance, safener or synergist, adjuvant and the plant protection product 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 has never been granted for the test or study report or that any period granted has not expired.	combination as defined in Article 51(1), except where the extension of authorisation is based on extrapolation, if the applications for such extensions are made by the authorisation holder at the latest five years after the date referred to in paragraph 5. 8. The same data protection rules as for the first authorisation shall also be granted to test and study reports submitted by third parties for the purpose of extension of authorisation for minor uses as referred to in Article 51(1). 9. Data protection shall be granted to test and study reports necessary for the renewal or review of an authorisation. The period for data protection shall be 30 months from the first renewal of the authorisation granted in accordance with 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) Article 65 – Labelling

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
		In Article 65, the following paragraph 4a new is added: ***“4. The labels of plant protection products shall include specific instructions for nursery production. Where biomass, planting density, or phenological stages differ significantly from adult crops in open fields, dosages shall be expressed in canopy volume units, per number of specimens, or per leaf area unit, in addition to or as an alternative to the dosage per hectare, to ensure treatment efficacy and compliance within digital record-keeping systems.”***	

36) Article 67 - Record-keeping

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1. Producers, suppliers, distributors, importers, and exporters of plant protection products shall keep records of the plant protection products they produce, import, export, store or place on the market for at least 5 years. Professional users of plant protection products shall, for at least 3 years, keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used. They shall make the relevant information contained in these records available to the competent authority on request. Third parties such as the drinking water industry, retailers or residents, may request access to this information by addressing the competent authority. The competent authorities shall provide access to such information in	'1. Producers, suppliers, distributors, importers, and exporters of plant protection products shall keep records of the plant protection products they produce, import, export, store or place on the market for at least 5 years. Professional users of plant protection products shall, except for plant protection products containing as active substances only biocontrol substances, for at least 3 years, keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used. They shall make the relevant information contained in these records available to the competent authority on request. Third parties such as the drinking water industry, retailers or residents may request access to this information	*'1. Producers,* ***Cooperatives of producers,*** *suppliers, distributors, importers, and exporters of plant protection products shall keep records of the plant protection products they produce, import, export, store or place on the market for at least 5 years. Professional users of plant protection products shall,* ~~*except for plant protection products containing as active substances only biocontrol substances,*~~ *for at least 3 years, keep records of the plant protection products they use, containing the name of the plant protection product, the day* ~~*time*~~ *and the dose of application, the area and the crop where the plant protection product was used.* ***Upon request of the competent authority, professional users*** ~~*They*~~ *shall make the relevant information contained in these records available to the competent authority* ~~*on request in case of*~~ *:*	

accordance with applicable national or Community law. By 14 December 2012, the Commission shall present a report to the European Parliament and the Council on the costs and benefits of the traceability of information from users to retailers concerning the applications of plant protection products on agricultural products, accompanied, if necessary, by appropriate legislative proposals. 2. Producers of plant protection products shall undertake post-authorisation monitoring on the request of the competent authorities. They shall notify the competent authorities of the relevant results. 3. Authorisation holders shall provide the competent authorities of the Member States with all data relating to the volume of sales of plant protection products in accordance with Community legislation concerning statistics on plant protection products. 4. Implementing measures to ensure the uniform application of paragraphs 1, 2 and 3 may be adopted in	by addressing the competent authority. The competent authorities shall provide access to such information in accordance with applicable national or Union law'.	***a) In case of a regulatory inspection carried out by the competent authority*** ***b) For the purpose of compiling agricultural statistics*** ***c) If there is a reasonable suspicion of a risk to human health or to the environment*** ~~*Third parties such as the drinking water industry, retailers or residents may request access to this information by addressing the competent authority.*~~ ***In the case described under point b) of this paragraph, anonymisation and aggregation of the data sets will be granted.***	

accordance with the regulatory procedure referred to in Article 79(3).			

37) Article 68 - Monitoring and control

Regulation (EC) 1107/2009	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Member States shall carry out official controls in order to enforce compliance with this Regulation. They shall finalise and transmit to the Commission a report on the scope and the results of these controls within six months of the end of the year to which the reports relate. Commission experts shall carry out general and specific audits in the Member States for purposes of verifying the official controls carried out by the Member States. A Regulation, adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4), shall set out provisions for the controls, in particular on the production, packaging, labelling, storage, transport, marketing, formulation, parallel trade and use of plant protection products. It shall also contain provisions concerning the collection of information and reporting on suspected poisonings.		

Article 2

Transitional provisions concerning Regulation (EC) No 1107/2009

1) Article 14(2) of Regulation (EC) No 1107/2009

Regulation (EC) 1107/2009
Article 14 – paragraph 2

Regulation (EC) 1107/2009	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
	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].	***Article 14(2) of Regulation (EC) No 1107/2009 as amended by [OP: please insert the reference of this Regulation] shall 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

3) Article 23a (6) of Regulation (EC) No 1107/2009

Article 3

Amendments to Regulation (EC) No 396/2005 (MRL)

1) Article 3 – Definitions

Regulation (EC) 396/2005	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
(a) 'good agricultural practice' (GAP) means the nationally recommended, authorised or registered safe use 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 Directive 91/414/EEC, of the 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;	'(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 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. ;		
(f) 'limit of determination' (LOD) means the validated lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods;	'(f) 'limit of quantification' (LOQ) means the validated lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods;';		
(g) 'import tolerance' means an MRL set for imported	point (g) is deleted;		

products to meet the needs of international trade where: — the use of the active substance in a plant protection product on a given product is not authorised in the Community for reasons other than public health reasons for the specific product and specific use; or — a different level is appropriate because the existing Community MRL was set for reasons other than public health reasons for the specific product and specific use;			

2) Article 6 - Applications

Regulation (EC) 396/2005	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
4. Applications for import tolerances shall be submitted to rapporteur Member States designated pursuant to Directive 91/414/EEC or, 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.	'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.’;		

3) Article 10 - The authority’s opinion on applications concerning MRLs

Regulation (EC) 396/2005	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
(b) the anticipated LOD for the pesticide/product combination;	‘(b) the anticipated LOQ for the pesticide/product combination;’;		

4) Article 14 - Decision on applications concerning MRLs

Regulation (EC) 396/2005	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
	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:* '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) Article 15 - Inclusion of new or modified MRLs in Annex II e III

Regulation (EC) 396/2005	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification

(c) in the cases mentioned in Article 16, set temporary MRLs and list them in Annex III to this Regulation.	~~(c) in the cases mentioned in Article 16, set temporary MRLs and list them in Annex III to this Regulation.~~		

6) Article 16 - Procedure for settings MRLs in certain circumstances

Regulation (EC) 396/2005	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1. The Regulation referred to in Article 14(1) may also set a temporary MRL to be included in Annex III in the following circumstances: (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 Article 8(4) of Directive 91/414/EEC; 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	1. The Commission may adopt a Regulation under Article 14(1) setting a MRL to be included in Annex III in the following circumstances: (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		

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, provided that no unacceptable safety concerns for the consumer have been identified. 2. The inclusion of temporary 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. The continued validity of the temporary MRLs referred to in paragraphs 1(a), (b), (c) and (d) shall be reassessed at least once every 10 years and any such MRLs shall be modified or deleted as appropriate. The MRLs referred to in paragraph 1(e) shall be reassessed at the expiry of the period for which the essential use was authorised. The MRLs referred to in paragraph 1(f)	(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, 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.’;		

shall be reassessed when the scientific studies have been completed and evaluated, but no later than four years after their inclusion in Annex III.			

7) In article 18 - Compliance with MRLs

Regulation (EC) 396/2005	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
	New para (1a) '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 - Information by the Member State

Regulation (EC) 396/2005	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
(b) the LODs applied in the national control programmes referred to in Article 30 and under the Community control programme referred to in Article 29;	'(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 - Scientific opinion of the authority

Regulation (EC) 396/2005	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
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.	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.		

Article 4

Amendments to Regulation (EU) No 528/2012 (Biocidal)

1) Article 4 - Condition for Approval

Regulation (EC) 528/2012	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1. An active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in point (b) of Article 19(1) taking into account the factors set out in Article 19(2) and (5). An active substance that falls under Article 5 may only be approved for an initial period not exceeding five years.	'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.’;		

2) Article 4 - Condition for Approval

Regulation (EC) 528/2012	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
(h) the date of approval and the expiry date of the approval of the active substance.	‘(h) the date of approval and, when appropriate, the expiry date of the approval of the active substance.’ ;		

3) Article 9 - Approval of an active substance

Regulation (EC) 528/2012	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
(a) adopt an implementing Regulation providing that an active substance is approved, and under which conditions, including the dates of approval and of expiry of the approval; or	‘(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) Article 10 - Active substance which are candidates for substitution

Regulation (EC) 528/2012	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification

4. By way of derogation from Article 4(1) and Article 12(3), 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.	'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) Article 12 - Condition of renewal

Regulation (EC) 528/2012	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
3. The renewal of an approval of an active substance shall be for 15 years for all product-types to which the approval applies, unless a shorter period is specified in the implementing regulation adopted in accordance with point (a) of Article 14(4) renewing such an approval	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 shorter period is specified in the implementing act adopted in accordance with Article 14(4), point (a), renewing such an approval.';		

6) Article 13 - Submission and acceptance of applications

Regulation (EC) 528/2012	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1. Applicants wishing to seek renewal of the approval of an active substance for one or more product-types shall submit an application to the Agency at least 550 days 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.	'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) New Article 14a - Renewal of an active substance with unlimited approval

Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
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 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) New Article 15a - Approval periods of active substance approved by *[OP, please insert the date: date of the entry into force of this Regulation]*

Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
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: (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) Article 44 - Evaluation of applications

Regulation (EC) 528/2012	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
5. On receipt of the opinion of the Agency, the Commission shall adopt either an implementing regulation granting the Union authorisation to the biocidal product or an implementing decision stating that the Union authorisation of the biocidal product has not been granted. Those implementing acts shall be adopted in	'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		

accordance with the examination procedure referred to in Article 82(3). 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).	examination procedure referred to in Article 82(3). Summaries of Commission decisions shall be published in the Official Journal of the European 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).’;		

10) Article 46 - Evaluation of applications for renewal

Regulation (EC) 528/2012	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification

4. On receipt of the opinion of the Agency, the Commission shall adopt either an implementing Regulation to renew the Union authorisation or an implementing decision to refuse to renew the Union authorisation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).	'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).'.		

Article 5

Amendment to Regulation (EC) No 1829/2003 (Additive)

1) In Article 2 - Definitions

Regulation (EC) No 1829/2003	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
	'produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs; in Article 2, point (10), the following is added 'Food and feed which are obtained using as production strains genetically modified micro-organisms within the meaning of Art 2(b) of Directive 2009/41/EC, with the		

	exception of animal and plant cells in culture, are not food and feed 'produced from GMOs' where they do not contain those micro-organisms and, if they contain residues thereof, such residues are limited to non-viable cells, their presence is minimized through reasonable attempts to remove them in accordance with good manufacturing practice and they have no technological effect on the food or the feed.'		

Article 6

Amendments to Regulation (EC) No 1831/2003 (Animal nutrition)

1) In Article 2 - Definitions

Regulation (EC) No 1831/2003	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1. For the purpose of this Regulation, the definitions of 'feed', 'feedingstuff', 'feed business', 'feed business operator', 'placing on the market' and 'traceability' laid down in Regulation	*1. For the purpose of this Regulation, the definitions of 'feed', 'feedingstuff', 'feed business', 'feed business operator', 'placing on the market' and 'traceability' laid down in Regulation (EC) No 178/2002 shall apply.*		

(EC) No 178/2002 shall apply. 2. The following definitions shall also apply: ***NEW POINTS ADDED BY COM***	*2. The following definitions shall also apply:* ‘‘(o) ‘label’ means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed on, or attached to the packaging or the container of the feed additive or premixture; (p) ‘labelling’ means the attribution of any words, particulars, trade marks, brand name, pictorial matter or symbol to a feed additive or a premixture by placing this information on any medium referring to or accompanying such feed additive or premixture, such as packaging, container, notice, label, document, ring, collar or digital means, including for advertising purposes.’; (q) ‘holder of the authorisation’ means the natural or legal person mentioned as such in the Community Register of Feed Additives in relation to the authorisation concerned.’;		

2) Article 3 - Placing on the market, processing and use

Regulation (EC) 1831/2003	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
3. In the case of additives belonging to categories (d) and (e) of Article 6(1) and of those additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from genetically modified organisms (GMOs), no person other than the holder of the authorisation named in the authorisation Regulation referred to in Article 9, his legal successor or successors, or a person acting under his written authority, shall first place the product on the market.	3. In the case of additives belonging to categories provided for under points (d) and (e) of Article 6(1) and of those additives falling within the scope of Union legislation relating to the marketing of products consisting of, containing or produced from genetically modified organisms (GMOs), no person other than the holder of the authorisation referred to in Article 9, his legal successor or successor in title, or a person acting under his written authority, shall first place the product on the market.’		

3) Article 9 - Authorisation by the Community

Regulation (EC) 1831/2003	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
6. A Regulation granting authorisation for additives belonging to categories (d) and (e) referred to in Article 6(1) and also for additives consisting of, containing or produced from GMOs, shall include the name of the holder of the authorisation, and, where appropriate, the unique identifier attributed to the GMO as referred to in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (2).	*paragraph 6 is replaced by the following:* '6. A Regulation granting authorisation for additives consisting of, containing or produced from GMOs shall include, where appropriate, the unique identifier attributed to the GMO as referred to in Regulation (EC) No 1830/2003 of the European Parliament and of the Council*';		

8. The authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 14. The authorised feed additive shall be entered in the Register referred to in Article 17 (hereinafter referred to as the Register). Each entry in the Register shall state the date of authorisation and shall include the particulars referred to in paragraphs 5, 6 and 7	*paragraph 8 is replaced by the following:* '8. Without prejudice to Article 13, the authorisation granted in accordance with the procedure laid down in this Regulation shall be valid for an unlimited period of time throughout the Union. The authorised feed additive shall be entered in the Community Register of Feed Additives referred to in Article 17 ('the Register')) upon the entry into force of the Regulation granting the authorisation. Each entry in the Register shall state the date of authorisation and shall include the particulars referred to in paragraphs 5, 6 and 7 of this Article. In addition, each entry in the Register concerning additives belonging to categories provided for under points (d) and (e) of Article 6(1), and additives consisting of, containing or produced from GMOs, shall include the name of the holder of the authorisation.';		

	the following paragraphs 8a and 8b are inserted: "8a. The Commission may, by means of implementing acts, amend the Regulations granting authorisations adopted before [OP: please insert the date = date of entry into force of this Regulation] which include the name of the respective holder of the authorisation, in order to remove such name and include it in the Register. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 22(2). 8b. By way of derogation from paragraph 8, the authorisation granted to additives belonging to the category provided for under point (e) of Article 6(1) in accordance with the procedure laid down in this Regulation shall be valid throughout the Union for 10 years and shall be renewable in accordance with Article 14.’.;		

4-5) New article 9a - Authorisation periods of certain authorisation granted before

Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Authorisation periods of certain authorisations granted before *[OP: please insert the date = date of entry into force of this Regulation]* Authorisations of feed additives granted before *[OP: please insert the date = date of entry into force of this Regulation],* shall be deemed to be unlimited in time, except for: (a) feed additives belonging to the category provided for in point (e) of Article 6(1); (b) urgent authorisations granted under Article 15; (c) authorisations for which no application for renewal has been submitted by the deadline set out in Article 14(1) before *[OP: please insert the date = date of entry into force of this Regulation]* or for which such application has been submitted but subsequently withdrawn;		

(d) authorisations for which an application for renewalhas been submitted in accordance with Article 14 before *[OP: please insert the date = date of entry into force of this Regulation]* and for which no decision has been taken by that date.’;		

6) Article 13 - Modification, suspension and revocation of authorisations

Regulation (EC) 1831/2003	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation still meets the conditions set out by this Regulation. It shall forthwith transmit this opinion to the Commission, to the Member States and, where applicable, to the holder of the authorisation. The opinion shall be made public.	1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation still meets the conditions set out in this Regulation, taking into account scientific and technological developments. In order to prepare its opinion, the Authority may, where appropriate, request the person who was the applicant for the authorisation concerned, or, where applicable, the holder of the authorisation, to submit within a specified time information and data relevant to the assessment. It shall forthwith transmit its opinion to the Commission, to the Member States and, where applicable, to the holder of		

2. The Commission shall examine the opinion of the Authority without delay. Any appropriate measures shall be taken in accordance with Articles 53 and 54 of Regulation (EC) No 178/2002. A decision on the modification, suspension or revocation of an authorisation shall be taken in accordance with the procedure referred to in Article 22(2) of this Regulation. 3. If the holder of the authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States. The Commission shall examine the opinion of the Authority without delay and decide in accordance with the procedure referred to in Article 22(2).	the authorisation. The opinion shall be made public. 2. The Commission shall examine the opinion of the Authority without delay. It shall, by means of implementing acts, take a decision on the modification, suspension or revocation of the authorisation concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 22(2). 3. If the holder of the authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States. The Commission shall examine the opinion of the Authority without delay and shall, by means of implementing acts, take a decision on the change concerned. Those implementing acts shall be adopted in accordance with the		

	examination procedure referred to in Article 22(2). 3a. Where a change concerning the holder of an existing authorisation needs to be made, the holder of that authorisation shall submit to the Commission any request for modification of the name of the holder of the authorisation, accompanied by the relevant data justifying the request. The Commission shall decide on the request for modification and shall notify the holder of the authorisation of its decision. Where the request is granted, the Commission shall adapt the relevant entry in the Register accordingly within 20 days.		
4. The Commission shall without delay inform the applicant of the decision taken. The Register shall be amended where appropriate.	4. In the case of authorisations not issued to a specific holder, any interested party may submit to the Commission an application for the modification of the terms of the authorisation, accompanied by the relevant data supporting the request for the change. Such modification shall aim to extend the specifications or conditions of the relevant authorisation. The Authority shall		

7) Article 14 - Renewal of authorisations

Regulation (EC) 1831/2003	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1. Authorisations under this Regulation shall be renewable for 10-year periods. An application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation. In the case of authorisations not issued to a specific holder, any person who first places the additive on the market or any other interested party may submit the application to the Commission and shall be considered as the applicant. In the case of authorisations issued to a specific holder, the holder of the authorisation or his legal successor or successors may submit the application to the Commission and shall be deemed to be the applicant. 2. At the time of application, the applicant shall send the following	1. Authorisations granted under this Regulation to additives belonging to the category provided for in point (e) of Article 6(1) may be renewed for 10-year periods. An application for renewal shall be sent to the Commission by the holder of the authorisation or his legal successor or successors, who shall be deemed to be the applicant, at the latest one year before the expiry date of the authorisation.		

particulars and documents directly to the Authority: (a) a copy of the authorisation for placing the feed additive on the market; (b) a report on the results of the post-market monitoring, if such monitoring requirements are included in the authorisation; (c) any other new information which has become available with regard to the evaluation of the safety in use of the feed additive and the risks of the feed additive to animals, humans or the environment; (d) where appropriate, a proposal for amending or supplementing the conditions of the original authorisation, *inter alia*, the conditions concerning future monitoring. 3. Articles 7(1), (2), (4) and (5), 8 and 9 shall apply accordingly. 4. Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall	2. At the same time as it sends the application, the applicant shall send the following to the Authority: (a) a reference to the current authorisation for placing the feed additive on the market; (b) a report on the results of the post-market monitoring, if such monitoring requirements are included in the authorisation; (c) any other new information which has become available since the adoption of the current authorisation, with regard to the evaluation of the safety in use of the feed additive and the risks of the feed additive to animals, humans or the environment; (d) where appropriate, a proposal for amending or supplementing the conditions of the current authorisation. 3. Articles 7, 8 and 9 shall apply accordingly. 4. Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall be automatically extended until the Commission takes a decision.		

automatically be extended until the Commission takes a decision. Information on this extension of the authorisation shall be made available to the public in the Register referred to in Article 17.	Information on such extension shall be made available to the public in the Register.’;		

8) New Article 14a - Rules for certain applications for renewal of authorization

Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Rules for certain applications for renewal of authorisations submitted before [*OP: please insert the date = date of entry into force of this Regulation*] The procedures concerning the applications for renewal of authorisations submitted in accordance with Article 14 before [*OP: please insert the date = date of entry into force of this Regulation*] and for which no decision has been taken by that date, shall be completed in accordance with Article 14 as it stood before that date. However, renewed authorisations concerned shall be valid for an unlimited period of time in accordance with Article 9(8).’;		

9) Article 16 - Labelling and packaging of feed additives and premixture

Regulation (EC) 1831/2003	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
No person shall place on the market a feed additive or a premixture of additives unless its packaging or container is labelled under the responsibility of a producer, packer, importer, seller or distributor established within the Community and bears the following information, in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member State in which it is marketed, in relation to each additive contained in the material:	The person responsible for the labelling shall be the feed business operator established within the Union who first places the feed additive or the premixture of additives on the market or, where applicable, the feed business operator under whose name or business name the feed additive or the premixture of additives is placed on the market. A feed additive or premixture of additives shall not be placed on the market unless a label is attached to its packaging or container and bears the following information, in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member State in which it is marketed, in relation to each additive contained in the material:		

(a) the specific name given to the additives upon authorisation, preceded by the name of the functional group as mentioned in the authorisation; (b) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this Article; (c) the net weight or, in the case of liquid additives andpremixtures, either the net volume or the net weight; (d) where appropriate, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC or the registration number assigned to the establishment or the intermediary pursuant to Article 10 of that Directive; (e) directions for use, and any safety recommendations regarding the use and, where applicable, the specific requirements mentioned in the	(a) the specific name given to the additives upon authorisation, preceded by the name of the functional group referred to in the authorisation; (b) the name or business name and the address or registered place of business of the person responsible for the labelling referred to in this Article, and, where the producer is not the person responsible for the labelling, the name or business name and address of the producer; (c) the net weight or, in the case of liquid additives and premixtures, either the net volume or the net weight; (d) where appropriate, the approval number of the establishment placing on the market, and where applicable, that of the establishment producing the additive or the premixture, pursuant to Article 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council68. (e) directions for use, any safety provisions or recommendations regarding the use and handling of the additive or premixtures mentioned in the authorisation, including animal species and categories for which the	*(b) the name or business name and the address or registered place of business of the person responsible for the labelling referred to in this Article,* ***~~and, where the producer is not the person responsible for the labelling, the name or business name and address of the producer;~~***	

authorisation, including animal species and categories for which the additive or premixture of additives is intended; (f) the identification number; (g) the batch reference number and date of manufacture. 2. For flavouring compounds, the list of additives may be replaced by the words ‘mixture of flavouring compounds’. This shall not apply to flavouring compounds subject to a quantitative limitation when used in feed and drinking water. 3. In addition to the information specified in paragraph 1, the packaging or container of an additive belonging to a functional group specified in Annex III must bear the information, presented in a conspicuous, clearly legible and indeliblemanner, indicated in that Annex. 4. Moreover, in the case of premixtures, the word ‘Premixture’ (in capital letters) must appear clearly on the label, and the carrier substance must be declared.	additive or premixture of additives is intended, and other specific labelling requirements laid down in the authorisation; (f) the identification number; (g) the batch reference number and date of manufacture. In the case of premixtures, points (b), (d), (e) and (g) shall not apply to the incorporated feed additives. By way of derogation from the first subparagraph, the information referred to in points (b), (d) and (g) may be provided by digital means 3. For flavouring compounds, the list of additives may be replaced by the words ‘mixture of flavouring compounds’. This shall not apply to flavouring compounds subject to a quantitative limitation when used in feed. 4. In addition to the information specified in paragraph 2, the label attached to the packaging or container of an additive belonging to a functional group specified in Annex III or of a premixture containing an additive belonging to a functional group specified in Annex III shall bear the information provided for in point 1,		

5. Additives and premixtures shall be marketed only in closed packages or closed containers which must be closed in such a way that the fastener is damaged on opening and cannot be re-used. 6. Amendments to Annex III to take technological progress and scientific development into account may be	point 2(a)(i) and 2(b)(i) of that Annex, presented in a conspicuous, clearly legible and indelible manner. 5. In the case of premixtures, the word 'premixture' shall appear on the label. Carriers shall be declared, in the case of feed materials, in compliance with Article 17(1)(e) of Regulation (EC) No 767/2009 , and, where water is used as a carrier, the moisture content of the premixture shall be declared. Only one minimum storage life may be indicated in respect of each premixture as a whole. Such minimum storage life shall be determined on the basis of the minimum storage life of each of its components. 6. Additives and premixtures shall be marketed only in closed packages or closed containers which shall be closed in such a way that the fastener is damaged upon opening and cannot be re-used. 7. The information provided by digital means shall be: (a) made available on a physical label to the competent authority upon request;		

adopted in accordance with the procedure referred to in Article 22(2).	(b) easily and directly accessible, free of charge, through all major operating systems and browsers, without a need to register in advance, to download or install applications or to provide a password, and accessible to all potential users in the Union and competent authorities for control; (c) made available for a period of two years from the date that the additive or premixture was placed on the market, including in the event of the insolvency, liquidation or cessation of activity in the Union of the economic operator that created it. 8. The Commission is empowered to adopt delegated acts in accordance with Article 21a amending Annex III to take technological progress and scientific development into account. 9. The Commission is empowered to adopt delegated acts in accordance with Article 21a in order to supplement this Regulation by establishing rules to enhance and facilitate labelling by the use of digital means. Those rules may relate in particular to the nature of the information concerned, which may include information referred to in		

	paragraphs 2, 4 and 5, or the type of digital means that may be used. Safety-critical and essential-use information, such as that included in the authorisation, shall remain on the label attached to the packaging or container referred to in paragraph 2.’;		

10) Article 21 - Reference laboratories

Regulation (EC) 1831/2003	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
Applicants for the authorisation of additives shall contribute to supporting the cost of the tasks of the Community Reference Laboratory and the consortium of National Reference Laboratories mentioned in Annex II. Detailed rules for implementing Annex II and any amendments to that Annex shall be adopted in accordance with the procedure referred to in Article 22(2).	2. The power to adopt delegated acts referred to in Article 3(5), Article 6(3), Article 7(5), Article 16(8) and Article 21 shall be conferred on the Commission for a period of five years from 26 July 2019. The power to adopt delegated acts referred to in Article 16(9) shall be conferred on the Commission for a period of five years from [*OP: please insert the date = date of entry into force of this Regulation]*. 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 3(5), Article 6(3), Article 7(5), Article 16(8) and (9) and Article 21 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.’;		

Article 7

Amendment to Regulation (EC) No 852/2004 (hygiene of foodstuffs)

1) Article 5 – the following paragraph 5a new is added:

Regulation (EC) 852/2004	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
	In accordance with the guidance document 2022/C 355/01, Member States shall ensure that small and medium-sized enterprises (SMEs) and retail establishments, where the hazard analysis does not identify specific critical control points (CCPs) or where the nature of the activity is simple may replace the formal documentation of HACCP procedures with the proportionate application of good hygiene practices (GHP/PRPs) and the simplified recording of critical non-compliances only.	

2) Article 13 - Amendment and adaptation of Annexes I and II

Regulation (EC) 852/2004	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
3 . Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7 of this Article, national measures adapting the requirements laid down in Annex II.	'3. Member States may, without compromising the achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 and 5 of this Article, national measures adapting the requirements laid down in Annex II.’;		

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. The notification shall: (a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought; (b) describe the foodstuffs and establishments concerned; (c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation; and (d) give any other relevant information.	5. Any Member States wishing to adopt national measures referred to in paragraph 3 shall notify the Commission in accordance with the procedure laid down in Articles 5 and 6 of Directive (EU) 2015/1535. The notification shall: (a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought; (b) describe the foodstuffs and establishments concerned; (c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation; and (d) provide any other relevant information.'; ~~(c) paragraphs 6 and 7 are deleted.~~		

Article 8

Amendment to Regulation (EC) No 853/2004 (specific hygiene rules for on the hygiene of foodstuffs)

1) Article 10 - Amendment and adaptation of Annexes II and III

Regulation (EC) 853/2004	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 8, national measures adapting the requirements laid down in Annex III. 5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. Each notification shall: (a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought; (b) describe the foodstuffs and establishments concerned;	'3. Member States may, without compromising the achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4, 5 and 8 of this Article, national measures adapting the requirements laid down in Annex III.'; 5. Any Member States wishing to adopt national measures referred to in paragraph 3 shall notify the Commission in accordance with the procedure laid down in Articles 5 and 6 of Directive (EU) 2015/1535. The notification shall: (a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;		

	(b) describe the foodstuffs and establishments concerned; (c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation; and (d) provide any other relevant information.'; (c) paragraphs 6 and 7 are deleted.		

Article 9

Amendment of Regulation (EC) No 1099/2009 (on the protection of animals at the time of killing)

1) In Regulation (EC) No 1099/2009 Article 18 - Depopulation, paragraphs 4 and 6 are deleted.

Article 10

Amendment to Regulation (EC) No 999/2001 (transmissible spongiform encephalopathies)

1) In Article 5, paragraph 3 - Classification, the third subparagraph is replaced by the following:

Regulation (EC) 999/2001	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
The rapid tests shall be approved for that purpose in accordance with the procedure referred to in Article 24(2) and entered on a list set out in Annex X, Chapter C, point 4.	'The Commission is empowered to adopt delegated acts in accordance with Article 23b for the purpose of approval of the rapid tests and to amend the list set out in Annex X, Chapter C, point 4'*;*		

2) Article 6 - Monitoring system

Regulation (EC) 999/2001	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1.Each Member State shall carry out an annual programme for monitoring BSE and scrapie in accordance with Annex III, Chapter A. That programme shall include a screening procedure using rapid tests. Rapid tests shall be approved for that purpose in accordance with the procedure referred to in Article 24(2)	'1. Each Member State shall carry out an annual monitoring programme for TSEs based on surveillance in accordance with Annex III. The Commission is empowered to adopt delegated acts in accordance with Article 23b for the purpose of approval of the rapid tests. The Commission is empowered to adopt delegated acts in accordance with Article 23b amending Annex X to list those tests.'; ~~Rapid tests shall be approved for that purpose in accordance with the procedure referred to in Article 24(2)~~		

and listed in Annex X, Chapter C, point 4.	~~and listed in Annex X, Chapter C, point 4~~ 1a. The annual monitoring programme referred to in paragraph 1 shall cover the animal subpopulations listed in Annex III. The Commission is empowered to adopt delegated acts in accordance with Article 23b to amend the provisions of that paragraph according to scientific progress and after consultation of the European Food Safety Authority.’;		

3) Article 8 - Specified risk material

Regulation (EC) 999/2001	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
1. The specified risk material shall be removed and destroyed in accordance with points 2, 3, 4 and 8 of Annex V. That specified risk material or the material processed therefrom may be placed on the market or, if need be, exported only for final destruction in accordance with points 3 and 4 or as appropriate 7(c) or 8 of Annex V. It may not be imported into the Community. Transit of specified risk material through Community	‘1. The specified risk material shall be removed in accordance with Annex V to this Regulation and disposed of in accordance with Regulation (EC) No 1069/2009. The Commission is empowered to adopt delegated acts in accordance with Article 23b to amend the list of specified risk material referred to in Annex V . Taking into account the different risk categories laid down in the first subparagraph of Article 5(1) and the requirements of Article 6(1a)		

territory must take place in accordance with the requirements of Article 3 of Directive 91/496/EEC.	and (1b) (b) the list of specified risk material in Annex V shall be amended accordingly. The specified risk material, referred to in first sub-paragraph, shall not be imported into the Union.'; 'The Commission is empowered to adopt delegated acts in accordance with Article 23b to amend the list of the approved alternative tests allowing to detect BSE prior to slaughter in Annex X. Paragraph 1 of this Article shall not apply to tissues from animals which have undergone the alternative test, provided that this test is applied under the conditions provided for in Annex V and the test results are negative.'; '5. The Commission is empowered to adopt delegated acts in accordance with Article 23b to amend the rules providing exemptions from paragraphs 1 to 4 of this Article, with regard to the date of the effective enforcement of the feeding prohibition provided for in Article 7(1) or, as appropriate for third countries or regions thereof with a controlled BSE risk, with regard to the date of the effective enforcement		
2. Paragraph 1 shall not apply to tissues from animals which have undergone an alternative test approved for that distinct purpose in accordance with the procedure referred to in Article 24(2) and listed in Annex X, Chapter C, point 5, and applied under the conditions listed in point 5 of Annex V — and where the results of the test were negative.			
5. By way of derogation from paragraphs 1 to 4, a decision may be adopted, in accordance with the procedure referred to in Article 24(2), with regard to the date of effective enforcement of Article 7(1) or, as appropriate, in the third countries, the date of banning the use of mammalian protein in feed for ruminants in each			

country or region placed in category 3 or 4, in order to limit the application of this Article to animals born before that date in those countries or regions.	of the ban of ruminant protein in feed for ruminants with a view to limiting the requirements to remove and destroy specified risk material to animals born before that date in the countries or regions concerned.’;		

4) Article 16 - Placing on the market of products of animal origin

Regulation (EC) 999/2001	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
(vii) collagen derived from the hides and skins referred to in point (v). 7. In accordance with the procedure referred to in Article 24(2), the provisions of paragraphs 1 to 6 may be extended to other products of animal origin. Rules for the implementation of this Article shall be adopted by the same procedure.	‘(b) milk and dairy products, hides and skins, and gelatine and collagen’; ‘7. The Commission is empowered to adopt delegated acts in accordance with Article 23b supplementing this Regulation to adapt the provisions of paragraphs 1 to 6’;		

5) Article 23 - Amendment of the annexes and transitional measures, a new paragraph 3 is inserted:

Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
‘3. Without prejudice to paragraphs 1 and 2, the Commission is empowered to adopt delegated acts in		

accordance with Article 23b amending the Annexes. The amendments shall have the aim of adapting the provisions contained in those annexes to the evolution of the epidemiological situation, of the available scientific knowledge, of the relevant international standards, of the available analytical methods for official controls or of the results of controls or studies on the implementation of those provisions and shall take into account the following criteria: i. where relevant, the conclusions of the available the Authority opinion; ii. the need to maintain a high level of protection of human and animal health in the Union.’;		

6) Article 23a, points (a), (b), (g), (h) and (k) and (m) are deleted.

Regulation (EC) 999/2001	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification

7) New Article 23b - Exercise of the delegation

Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification

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 6(1) and (1a), Article 8(1), (2), and (5), and Article 16(7) and Article 23 (3) shall be conferred for an indeterminate period of time from the date of the entry into force of this Regulation. 3. The delegation of powers referred to in Article 5(3), Article 6(1) and (1a), Article 8(1), (2), and (5), and Article 16(7) and Article 23 (3) 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 on Better-Law-making of 13 April 2016. 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 6(1) and (1a), Article 8(1), (2), and (5), and Article 16(7) and Article 23 (3) 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 the Council.'.		

Article 11

Amendment to Regulation (EU) 2017/625

1) Article 41- Powers to adopt derogations from the condition for the mandatory accreditation of all the methods of laboratory analysis, test and diagnosis used by official laboratories, is replaced

Regulation (EU) 2017/625	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where, and the conditions under which, competent authorities may designate as official laboratories, in accordance with Article 37(1), laboratories which do not fulfil the	The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where, and the conditions under which, competent authorities may designate as official laboratories, in accordance with Article 37(1), laboratories which do not fulfil:	*The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where, and the conditions under which, competent authorities may designate as official laboratories, in accordance with Article 37(1),*	

conditions referred to in point (e) of Article 37(4) in relation to all the methods they use for official controls or other official activities, provided that such laboratories comply with the following conditions: (a)they operate and are accredited in accordance with the standard EN ISO/IEC 17025 for the use of one or more methods which are similar to and representative of the other methods they use; and (b)they make regular and significant use of the methods for which they have obtained the accreditation referred to in point (a) of this Article; except, as regards the area governed by the rules referred to in point (g) of Article 1(2), where a validated method for the detection of the particular pests of plants referred to in Article 34(1) and (2) does not exist.	(a) the condition referred to in point (e) of Article 37(4) in relation to the standards in accordance with which the laboratories operate and are accredited; and (b) the condition referred to in point (a) of Article 37(5) in relation to the accreditation for all the methods they use for official controls or other official activities, provided that such laboratories comply with the following conditions: i. they operate and are accredited in accordance with the standard EN ISO/IEC 17025 or with the standard defined in accordance with point (a) for the use of one or more methods which are similar to and representative of the other methods they use; and ii. they make regular and significant use of the methods for which they have obtained the accreditation referred to in point (i) ; except, as regards the area governed by the rules referred to in point (g) of Article 1(2), where a validated method for the detection of the particular pests of plants referred to in Article 34(1) and (2) does not exist.'; (a) the condition referred to in point (e) of Article 37(4) in relation to the standards in accordance with which the laboratories operate and are accredited; and (b) the condition referred to in point (a) of Article 37(5) in relation to the accreditation for all the methods they use for official controls or other official activities, provided that such laboratories comply with the following conditions: i. they operate and are accredited in accordance with the standard EN ISO/IEC 17025 or with the standard defined in accordance with point (a) for the use of one or more methods which are similar to and representative of the other methods they use; and	***in duly justified and exceptional cases and for a limited period of time,*** *laboratories which do not fulfil:* (a) *the condition referred to in point (e) of Article 37(4) in relation to the standards in accordance with which the laboratories operate and are accredited; and* (b) *the condition referred to in point (a) of Article 37(5) in relation to the accreditation for all the methods they use for official controls or other official activities, provided that such laboratories comply with the following conditions:* i. *they operate and are accredited in accordance with the standard EN ISO/IEC 17025 or with the standard defined in accordance with point (a) for the use of one or more methods which are similar to and representative of the other methods they use; and*	

		ii. *they make regular and significant use of the methods for which they have obtained the accreditation referred to in point (i)* ***and use harmonised EU guidelines for the internal validation of analytical methods****; except, as regards the area governed by the rules referred to in point (g) of Article 1(2), where a validated method for the detection of the particular pests of plants referred to in Article 34(1) and (2) does not exist.';*	

2) In **Article 50 - Certificates and documents accompanying consignments and split consignment, paragraph 3 is replaced**

Regulation (EU) 2017/625	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
3.Consignments shall not be split until official controls have been performed and the Common Health Entry Document (CHED) referred to in Article 56 has been finalised in	'3. Consignments shall not be split until official controls have been performed and the Common Health Entry Document (CHED) referred to in Article 56 has been finalised in		

accordance with Article 56(5) and Article 57.	accordance with Article 56(5) and Article 57, unless requested by the competent authorities in the case of consignments of goods referred to in Article 47(1)(c) for the purposes of performing physical checks on only part of a consignment presented at a border control post.’;		

In paragraph 1 of article 56 of Regulation 2017/625, a second subparagraph is added:

Regulation (EU) 2017/625	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification

After paragraph 3 of article 57 of Regulation 2017/625, a new paragraph is added:

Regulation (EU) 2017/625	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification

3) In Article 93 - Designation of European Union reference laboratories, paragraph 4 is replaced

Regulation (EU) 2017/625	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
4.By way of derogation from point (a) of paragraph 3 of this Article, for the area governed by the rules referred to in point (g) of Article 1(2), the Commission may designate official laboratories, designated as such by the competent authorities on the basis of a derogation adopted pursuant to Article 41, as European Union reference laboratories irrespective of whether they fulfil the conditions provided for in point (a) of paragraph 3 of this Article.	'4. By way of derogation from point (a) of paragraph 3, the Commission may designate European Union reference laboratories whether or not those laboratories fulfil the conditions provided for in that point in relation to: (a) the standards in accordance with which the laboratories operate and are accredited; and (b) the accreditation for all the methods of laboratory analysis, test and diagnosis that the laboratories use. The Commission may designate such laboratories provided that they fulfil the conditions set out in the delegated acts adopted in accordance with paragraph 4a. 4a. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the establishment of the conditions to be fulfilled by laboratories to be designated European Union reference laboratories in accordance with paragraph 4.';		

4) Article 100 - Designation of national reference laboratories, is amended

Regulation (EU) 2017/625	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
2.The requirements provided for in point (e) of Article 37(4), Article 37(5), Article 39 and Article 42(1), points (a) and (b) of Article 42(2) and Article 42(3) shall apply to national reference laboratories.	'2. The requirements provided for in Article 37(4), point (e), Article 37(5), Article 39 and Article 42, paragraph 1, paragraph 2, points (a) and (b), and paragraph 3, shall apply to national reference laboratories.'; (ii) the second subparagraph is deleted;		
By way of derogation from point (e) of Article 37(4), for the area governed by the rules referred to in point (g) of Article 1 (2), competent authorities may designate official laboratories, designated as such by the competent authorities on the basis of a derogation adopted under Article 41, as national reference laboratories irrespective of whether they fulfil the condition provided for in point (e) of Article 37(4).	'6. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where, and the conditions under which competent authorities may designate national reference laboratories whether or not the laboratories fulfil the condition provided for in point (e) of Article 37(4) in relation to the standards in accordance with which the laboratories operate and are accredited and the condition provided for in point (a) of Article 37(5) in		

	relation to the accreditation for all the methods of laboratory analysis, test and diagnosis that the laboratories use.’;		

5) Article 144 - Exercise of the delegation, is amended

Regulation (EU) 2017/625	Commission Proposal - 2025/0410 (COD)	Draft Report – DORFMANN (AGRI)-PICARO (ENVI)	Justification
2.The power to adopt delegated acts referred to in Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) shall be conferred on the Commission for a period of five years from 28 April 2017. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the	‘2. The power to adopt delegated acts referred to in Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 93(4a), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) shall be conferred on the Commission for a period of five years from 28 April 2017. The Commission shall draw up a report in respect 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 Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) 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.	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 Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 93(4a), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) 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*		

6.A delegated act adopted pursuant to Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) 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 to 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.	*of any delegated acts already in force.';* *'6. A delegated act adopted pursuant to Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 99(2), 93(4a), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) 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 to 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.'.*		

Article 12

Entry into force and application

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