



Council of the  
European Union

Brussels, 17 December 2025  
(OR. en)

16969/25

---

---

**Interinstitutional File:  
2025/0417 (COD)**

---

---

**AGRI 729  
AGRILEG 209  
CODEC 2163**

**PROPOSAL**

---

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 16 December 2025

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

---

No. Cion doc.: COM(2025) 780 final

---

Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2018/848 as regards certain production, labelling and certification rules and certain rules on trade with third countries

---

Delegations will find attached document COM(2025) 780 final.

---

Encl.: COM(2025) 780 final



Brussels, 16.12.2025  
COM(2025) 780 final

2025/0417 (COD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Regulation (EU) 2018/848 as regards certain production, labelling and certification rules and certain rules on trade with third countries**

{SWD(2025) 424 final}

(Text with EEA relevance)

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

#### • **Reasons for and objectives of the proposal**

Organic farming is a key element of the Common Agricultural Policy (CAP) of the European Union. The share of land farmed organically has been steadily growing to 11% today. Consumers increasingly purchase organic food, recognisable through an EU logo and a common label. The production and labelling of organic products are governed by Regulation (EU) 2018/848, applicable since January 2022, and the delegated and implementing Regulations adopted on its basis. These regulations establish the detailed rules that underpin organic production.

In its judgment in Case C-240/23, the Court of Justice of the European Union concluded that, in light of the wording of Articles 30(2) and 33(1) of Regulation (EU) 2018/848, the context and the objectives of the legislation of which those provisions form part, neither terms referring to organic production nor the EU organic production logo may be used by products that comply only with standards merely equivalent to the production rules in Regulation (EU) 2018/848. It is therefore necessary to ensure that consumers are able to make informed choices when purchasing products from third countries whose organic production and control systems have been recognised as equivalent to those of the Union, as well as to ensure consumer confidence in those products and in the organic production logo of the European Union whilst ensuring fair competition within the internal market between products that fully comply with Union production and control rules and those that comply with rules equivalent to those Union rules.

Furthermore, given that the recognition of third countries whose organic production and control systems have been recognised as equivalent to those of the Union will expire on 31 December 2026 and that technical exchanges with those third countries with a view to concluding agreements on trade in organic products are still ongoing, it is necessary and urgent for those third countries to continue to be recognised until 31 December 2036 to avoid disruptions in the trade of organic products.

Finally, while Regulation (EU) 2018/848 provides a sound basis for a reliable and growing organic sector in the Union, it is necessary to make targeted adjustments to certain production rules to create a more efficient, effective, and user-friendly regulatory framework.

#### • **Consistency with existing policy provisions in the policy area**

This proposed regulation amends the current rules to facilitate organic production, labelling, controls and trade across the Union and in third countries. It will also ensure that consumers can make informed choices when buying organic products imported from third countries.

#### • **Consistency with other Union policies**

This proposal amends existing provisions of Regulation (EU) 2018/848, without altering their essence. As those existing provisions are consistent with other Union policies, the proposal is also consistent with those policies.

The proposal ensures that consumers can make informed choices as regards organic products imported from third countries whose organic production and control systems have been recognised as equivalent to those of the Union, in particular when bearing the organic production logo of the European Union and the terms referring to organic production. It also extends the deadline for the expiry of the recognition of third countries that were recognised

for the purposes of equivalence under Article 33(2) of Regulation (EC) No 834/2007. Finally, in reducing complexities in the regulatory burden on organic operators, this proposal may facilitate investments and lead to the development of employment opportunities in the organic sector, as well as the further development of agricultural practices with high environmental standards.

## **2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY**

### **• Legal basis**

Article 43(2) of the Treaty on the Functioning of the European Union.

### **• Subsidiarity (for non-exclusive competence)**

This proposal amends provisions of Regulation (EU) 2018/848. That Regulation was adopted at EU level and is applicable in all Member States.

The proposal, removes burdens on Member States, operators in the Union and in third countries and avoids the disruption of trade in organic products, by: (i) allowing the use of the products and substances available on the market for cleaning and disinfection for use in processing and storage; (ii) ensuring that consumers get appropriate information when purchasing products bearing the organic production logo of the European Union and the terms referring to organic production; (iii) adapting the conditions for the exemption of smaller operators selling unpacked organic products other than feed from the obligation of being in possession of a certificate pursuant to Article 35(1) of Regulation (EU) 2018/848; (iv) adapting the requirements for the composition of groups of operators; (v) postponing the expiry of recognition of equivalent third countries; and (vi) adapting livestock production rules.

The amendments maintain the degree of harmonisation already achieved by Regulation (EU) 2018/848 and ensure a level-playing field between operators in the organic sector. It is therefore considered that they cannot be implemented by Member States acting alone.

### **• Proportionality**

The proposal amends Regulation (EU) 2018/848 only to the extent strictly necessary to achieve the objectives of that Regulation, while ensuring that the amendments remain targeted and within the limit of what is necessary to achieve those objectives. It reduces the administrative burden on Member States and operators, and it adds new elements only to the extent strictly necessary to adjust Regulation (EU) 2018/848 to the objectives outlined above.

The proposal amends specific aspects of a limited number of provisions in Regulation (EU) 2018/848: (i) it allows operators to use the products and substances available on the market for cleaning and disinfection for use in processing and storage. This amendment does not change the objectives pursued by Regulation (EU) 2018/848 and only adjusts the provisions to the needs of the sector and to these objectives; (ii) it adapts rules on labelling of organic products imported from third countries. This amendment ensures that consumers are able to make informed choices when purchasing products from third countries whose organic production and control systems have been recognised as equivalent to those of the Union, as well as to ensure consumer confidence in those products and in the organic production logo of the European Union whilst ensuring fair competition within the internal market between products that fully comply with Union production and control rules and those that comply with rules equivalent to those Union rules; (iii) it adapts the conditions for the exemption of smaller operators who sell unpacked organic products other than feed from the obligation of being in possession of a certificate pursuant to Article 35(1) of Regulation (EU) 2018/848.

This amendment facilitates the exemption of smaller operators and therefore facilitates the achievement of the objective of Regulation (EU) 2018/848 of encouraging short distribution channels and local production in the various areas of the Union; (iv) it adapts and simplifies the requirements for the composition of groups of operators. This amendment facilitates the implementation of the existing provisions and the development of organic farming in accordance with Regulation (EU) 2018/848; (v) it postpones the expiry of the recognition of equivalent third countries. This amendment avoids any disruption in the trade of organic products and ensures a smooth transition to the scheme of recognition of third countries through international agreements; and (vi) it adapts production rules for livestock. This amendment, which aims to simplify the current rules and adapt them to the needs of the operators, is proportionate in so far as the new elements added to the EU organic legislative framework (such as the specific conversion period and the minimum age at slaughter for quails) are limited to the extent strictly necessary to adjust the existing provisions to the objectives outlined above.

- **Choice of the instrument**

The rules that need to be amended are laid down in a Regulation of the European Parliament and of the Council. Therefore, the chosen instrument must also be a Regulation of European Parliament and of the Council.

### **3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS**

- **Ex-post evaluations/fitness checks of existing legislation**

No evaluation or fitness check was performed on Regulation (EU) 2018/848. However, since January 2022 and the entry into application of Regulation (EU) 2018/848, the Commission consulted Member States and stakeholders on the implementation of the regulation.

- **Stakeholder consultations**

The Commission regularly exchanges information with Member States through the Group of Experts on Organic Production (GREX) and with stakeholders, through the Civil Dialogue Group on organic farming (CDG). In these meetings, the Commission gathers views on various aspects related to the implementation of Regulation (EU) 2018/848 and the delegated and implementing Regulations adopted on its basis.

In 2024, the Fit For Future Platform, the high-level expert group set up to help the Commission simplify existing legislation and reduce administrative burden, issued an opinion on how Regulation (EU) 2018/848 and the delegated and implementing Regulations adopted on its basis could be simplified<sup>1</sup>. The opinion was discussed in the AGRIFISH Council of 27 January 2025.

The Commission consulted the GREX and the CDG in the first half of 2025 to follow up on the opinion of that platform. It was concluded that some elements of Regulation (EU) 2018/848 and the delegated and implementing Regulations adopted on its basis could be simplified.

Furthermore, on 24 September 2025, a combined GREX-CDG meeting was held to discuss how Regulation (EU) 2018/848 could be simplified without lowering its objectives, principles and standards.

---

<sup>1</sup> [https://commission.europa.eu/document/download/25d40cdf-9e5e-4a8b-8da6-7a72efad04ed\\_en?filename=fo\\_2024\\_8\\_organic\\_production\\_and\\_labeling\\_en.pdf&prefLang=mt](https://commission.europa.eu/document/download/25d40cdf-9e5e-4a8b-8da6-7a72efad04ed_en?filename=fo_2024_8_organic_production_and_labeling_en.pdf&prefLang=mt)

An Implementation Dialogue on the organic policy<sup>2</sup> was held on 10 November 2025, chaired by the Commissioner for Agriculture and Food and attended by several agri-food organic operators and other stakeholders. Discussions focused on their experience of the rules on organic production and the labelling of organic products and how certain aspects of Regulation (EU) 2018/848 and the delegated and implementing Regulations adopted on its basis could be simplified.

Finally, a Call for evidence was open from 21 October to 18 November 2025<sup>3</sup>. A total of 720 submissions were received from EU citizens (44.9%), companies/businesses (31.3%), business associations (11%), Non-Governmental Organisations (NGOs) (2.8%), public authorities (1.5%), trade unions (1.3%), and others (7.4%). The feedback concerned possible amendments to Regulation (EU) 2018/848 and the delegated and implementing Regulations adopted on its basis.

- **Collection and use of expertise**

The Commission regularly exchanges views with Member States and stakeholders on the implementation of Regulation (EU) 2018/848 and the delegated and implementing Regulations adopted on its basis, including gathering feedback on difficulties they encounter. In addition, the Commission collected evidence through the targeted consultations mentioned above. The expertise gathered through all these consultations constitute the expertise the Commission relied on for this initiative.

- **Impact assessment**

In light of the need to urgently: (i) ensure that consumers are able to make informed choices when purchasing products from third countries whose organic production and control systems have been recognised as equivalent to those of the Union, as well as to ensure consumer confidence in those products and in the organic production logo of the European Union whilst ensuring fair competition within the internal market between products that fully comply with Union production and control rules and those that comply with rules equivalent to those Union rules; (ii) avoid any disruption of trade in organic products with third countries recognised as equivalent; (iii) address, in a targeted way, the challenges that the organic sector is facing, removing burdens and enhancing its competitiveness, no impact assessment could be conducted.

However, the proposed amendments to Regulation (EU) 2018/848 have been developed on the basis of the evidence gathered through consultations described in the section ‘Stakeholder consultations’ above. The proposed amendments are targeted and will not alter the overall objectives of the policy.

The full impact of the proposal will depend on the adherence to the proposed measures by organic operators. Beyond reduction of monetary costs, removing barriers for operators in the Union and in third countries is expected to stimulate the maintenance and the uptake of organic farming, thus enhancing its environmental and social benefits.

---

<sup>2</sup> [https://agriculture.ec.europa.eu/media/events/implementation-dialogue-eu-organic-policy-2025-11-10\\_en](https://agriculture.ec.europa.eu/media/events/implementation-dialogue-eu-organic-policy-2025-11-10_en)

<sup>3</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/15273-Organic-production-targeted-updates-and-simplification\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/15273-Organic-production-targeted-updates-and-simplification_en)

The Commission will present the reduction of burden, including an assessment of costs and benefits and how the inputs from the consultations have been taken into account, in an analytical Staff Working Document to be published along with this proposal.

Given that the proposed measures are expected to result in no increase in greenhouse gas emissions, this proposal is consistent with the climate-neutrality objective set out in Article 2(1) of Regulation (EU) 2021/1119 of the European Parliament and of the Council (European Climate Law), as well as the Union 2030<sup>4</sup> and 2040<sup>5</sup> climate targets. Moreover, as organic farming practices can strengthen resilience to climate change<sup>6</sup>, the proposed measures contribute to the EU's efforts in climate change adaptation, provided for in Article 5 of Regulation (EU) 2021/1119.

- **Regulatory fitness and simplification**

Several elements in the proposal contribute to simplification, reducing bureaucracy and administrative burden for organic operators and Member States' administrations (i) allowing the use of the products and substances available on the market for cleaning and disinfection for use in processing and storage; (ii) adapting the conditions for the exemption of smaller operators selling unpacked organic products other than feed from the obligation of being in possession of a certificate pursuant to Article 35(1) of Regulation (EU) 2018/848; (iii) adapting the requirements for the composition of groups of operators; and (iv) adapting livestock production rules. Moreover, they benefit Member States' administration in relation to the adaptation of the conditions for the exemption of smaller operators selling unpacked organic products other than feed from the obligation of being in possession of a certificate pursuant to Article 35(1) of Regulation (EU) 2018/848.

These elements therefore adapt the provisions of Regulation (EU) 2018/848 to the practical needs of operators, preserving objectives and principles of that Regulation, maintaining its high standards and avoiding one-size-fits-all approaches that might prove to be burdensome to implement and less effective.

In particular, these elements may entail annual direct administrative cost savings for a total of EUR 47.8 million, of which EUR 45.9 million for businesses and EUR 1.9 million for administrations. In addition, these elements may entail for businesses direct one-off adjustment cost savings of EUR 109.2 million and annual direct adjustment cost savings of EUR 90.2 million.

Following the digital assessment, the current proposal does not include any requirements of digital relevance. Digital means or data exchange are not under the scope of this proposal.

- **Fundamental rights**

The proposal respects the fundamental rights and observes the principles recognised, in particular, by the Charter of Fundamental Rights of the European Union.

---

<sup>4</sup> [https://climate.ec.europa.eu/eu-action/climate-strategies-targets/2030-climate-targets\\_en](https://climate.ec.europa.eu/eu-action/climate-strategies-targets/2030-climate-targets_en)

<sup>5</sup> Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2021/1119 establishing the framework for achieving climate neutrality (COM/2025/524 final) [https://climate.ec.europa.eu/document/download/e1b5a957-c6b9-4cb2-a247-bd28bf675db6\\_en](https://climate.ec.europa.eu/document/download/e1b5a957-c6b9-4cb2-a247-bd28bf675db6_en)

<sup>6</sup> N. Scialabba, M. Müller-Lindenlauf, Organic agriculture and climate change, Renewable Agriculture and Food Systems, 25 (2), pp. 158 – 169 (2010) 10.1017/S1742170510000116

#### 4. BUDGETARY IMPLICATIONS

This proposal has no budgetary implications.

#### 5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The market observatories established by the Commission continuously monitor the supply and demand of organic products, as well as their prices, on the Union market. They will continue to provide an insight on their developments. In addition, the Commission will continue to monitor the implementation of Regulation (EU) 2018/848 and the delegated and implementing Regulations adopted on its basis in the framework of its regular meetings with Member States and stakeholders' representatives. Finally, in relation to third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007, the Commission will continue to ensure their appropriate supervision as provided for in Article 48 of Regulation (EU) 2018/848.

- **Explanatory documents (for directives)**

Not applicable.

- **Detailed explanation of the specific provisions of the proposal**

In Case C-240/23 Herbaria Kräuterparadies II, the Court of Justice of the European Union (ECJ) ruled that Regulation (EU) 2018/848 must be interpreted as meaning that a product imported from a third country whose organic production and control systems have been recognised as equivalent to those of the Union, either through an international agreement between the Union and those third countries or where the third countries were recognised for the purpose of equivalence under Regulation (EC) No 834/2007, may not have on its labelling either the organic production logo of the European Union or, in principle, terms referring to organic production. The ECJ further ruled that the use of organic production logo of the third country from which such product comes should be permitted on the product, even where that logo contains terms identical to those referring to organic production, within the meaning of Article 30(1) of that Regulation (EU) 2018/848 and Annex IV thereto.

The use, for a product imported from a third country whose organic production and control systems have been recognised as equivalent to those of the Union, of the organic production logo of a third country is not liable to harm fair competition within the internal market in organic products or to give rise to ambiguity that may mislead consumers. This is because such a logo neither places the product concerned on the same level as Union organic products from the point of view of competition nor is liable to give the impression that the product concerned complies with all the requirements laid down by Regulation (EU) 2018/848.

Terms referring to organic production, including their derivatives and diminutives, are used both in the Union and in third countries to suggest to the purchaser that the product and its ingredients have been produced in accordance with applicable organic production methods. This is also the case in the Codex Alimentarius guidelines CAC/GL 32, where terms referring to organic production methods such as 'organic', 'biological', 'ecological' or words of similar intent including diminutives are used to suggest to the purchaser that the product or its ingredients were produced in accordance with organic production methods. In addition, certain organic production rules in third countries require terms referring to organic production to be used for products and their ingredients product that have been produced in accordance with applicable organic production methods.

Not every third country whose organic production and control systems have been recognised as equivalent to those of the Union has its own organic production logo. Consequently, if products from such third countries could not bear terms referring to organic production, this would deprive operators in those third countries of the possibility to indicate the organic status of such products and to suggest to consumers in the Union that those products originate from organic production and are produced in accordance with organic production methods in their countries of origin. This would also be difficult to reconcile with the Codex Alimentarius guidelines CAC/GL 32 because it would not be possible to refer to organic production methods in the labelling of such products despite them meeting all the corresponding conditions set out in these guidelines.

The recognition of the organic production and control systems of a third country as equivalent to those of the Union means that such a system has been assessed as meeting the same objectives and principles as those of the Union by applying rules which ensure the same level of assurance of conformity, even if that is achieved through different means.

Differences between the rules applied in organic production and control systems of third countries recognised as equivalent and those applied in the Union are intrinsic to the equivalence regime. The assessment of equivalency by the Commission has shown that while some of those differences are limited and do not translate into product characteristics, other differences involve rules of organic production which play an important role in the structure of organic production in the Union and contribute to achieving the objective of satisfying consumer expectations as regards organic products whilst ensuring fair competition within the internal market between products that fully comply with Union production and control rules and those that comply with rules equivalent to those Union rules. Those rules include living soil, animal welfare standards and processing of food using minimum artificial inputs.

A Eurobarometer survey<sup>7</sup> conducted in June and July 2024 and entitled ‘Europeans, Agriculture and the CAP’ indicated that the organic production logo of the European Union is the food product logo of which Europeans are the most aware. It is essential to both consumers and producers because it makes it easier for consumers to identify organic products and helps producers to market them across the Union.

In order to ensure a fair competition within the internal market between products that fully comply with Union production and control rules and those that comply with rules equivalent to those Union rules, and in order to respond to consumer expectations that products imported from third countries whose organic production and control systems have been recognised as equivalent to those of the Union meet standards as high as those of the Union, the use of the organic production logo of the European Union should be allowed in the labelling, presentation and advertising of products imported from those third countries, provided that, in addition to those equivalent rules, those products comply with certain additional production and control requirements.

In order to preserve the effectiveness of Regulation (EU) 2018/848 as regards trade with third countries, such additional requirements should correspond to production and control rules that play an important role in the structure of organic production in the Union and contribute to achieving the objective of satisfying consumer expectations as regards organic products whilst ensuring fair competition within the internal market.

Where there are changes to the production rules in the EU or in third countries whose organic production systems have been recognised as equivalent to those of the Union, the power to

---

<sup>7</sup> <https://europa.eu/eurobarometer/surveys/detail/3226>

adopt certain acts should be delegated to the Commission in respect of adding or amending the additional production and control requirements with which products imported from those third countries must comply in order to use the organic production logo of the European Union.

Operators in the Union that produce organic food and feed rely on the use of ingredients imported from third countries whose organic production and control systems have been recognised as equivalent to those of the Union. Such ingredients are used in variable proportions during the processing of organic products in the Union and are necessary for a large variety of organic products processed in the Union.

Processing operations in the Union, when using those ingredients, take place in compliance with the production rules set out in Regulation (EU) 2018/848. The use of the organic production logo of the European Union should therefore be allowed by products processed in the Union and that contain organic ingredients either produced in accordance with this Regulation or imported from third countries whose organic production and control systems have been recognised as equivalent to those of the Union and where those ingredients account for 5% or less of the agricultural ingredients of the product (by weight for food and in general for feed).

Where those ingredients account for more than 5% of the agricultural ingredients of the product (by weight for food and in general for feed), and in order to ensure a fair competition between processed products containing ingredients that fully comply with Union production and control rules and those that comply with rules equivalent to those Union rules, and in order to respond to consumer expectations in relation to the use of the organic production logo of the European Union, that logo should be allowed in the labelling, presentation and advertising of processed products containing ingredients imported from those third countries, provided that, in addition to those equivalent rules, those ingredients comply with certain additional production and control requirements.

Regulation (EU) 2018/848 provides that the use of the organic production logo of the European Union is obligatory for all organic prepacked food produced within the Union. It is therefore necessary to exclude from that obligation prepacked food produced within the Union with ingredients imported from third countries whose organic production and control systems have been recognised as equivalent to those of the Union and where those ingredients account for more than 5% of the agricultural ingredients of the product by weight and do not comply with certain additional production and control requirements.

The recognition of third countries whose organic production and control systems have been recognised as equivalent to those of the Union will expire on 31 December 2026. On 28 June 2021, the Council authorised the Commission to open negotiations with the third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007 with a view to concluding agreements on trade in organic products. On that basis, the Commission is conducting technical exchanges with those third countries. Those exchanges show different levels of progress due to the diversity of legal and regulatory frameworks and complexities linked to varying consumer perceptions of organic production from one organic production system to the other. It is therefore necessary and urgent for those third countries to continue to be recognised until 31 December 2036 to avoid disruptions in the trade of organic products.

Regulation (EU) 2018/848 provides that products for cleaning and disinfection in processing and storage facilities for use in organic production should be authorised and included in restrictive lists by the Commission. However, there are a number of challenges associated with the establishment of such lists. Those challenges have been confirmed by several reports from the Expert Group for Technical Advice on Organic Production (EGTOP). First, there are

a large number of products and substances for cleaning and disinfection of processing and storage facilities currently available on the Union market. Second, the processing and storage of organic products takes place in many different types of establishments and involves the use of a wide range of equipment, machinery and buildings. Third, the equipment and machinery for processing and storage must be cleaned and disinfected in accordance with the manufacturers' specifications in order to ensure its appropriate maintenance and operation. With a view to allowing organic operators to use products and substances for cleaning and disinfectants available on the market, the requirement for the Commission to authorise products for cleaning and disinfection in processing and storage facilities for use in organic production and include them in restrictive lists should be deleted.

Regulation (EU) 2018/848 entitles Member States to exempt smaller operators that sell unpacked organic products other than feed from the obligation to be in the possession of a certificate pursuant to Article 35(1) of Regulation (EU) 2018/848. However, the current conditions may act as a barrier to growth. Furthermore, increasing costs experienced by smaller operators since the entry into application of Regulation (EU) 2018/848 have increased their turnover in relation to unpacked organic products other than feed. This has created a barrier to the fulfilment of the conditions relating to their turnover in order to be exempted from the obligation of being in possession of a certificate pursuant to Article 35(1). Those conditions should therefore be abolished. In addition, the condition relating to annual sales should be revised upwards in order not to hinder smaller operators from being exempted from the obligation of being in possession of a certificate pursuant to Article 35(1).

Regulation (EU) 2018/848 lays down provisions on the composition of groups of operators in the Union and in third countries. Evidence in relation to the implementation of those provisions shows significant difficulties in setting up groups of operators that fulfil requirements as regards the composition of members, in particular the annual turnover, and as regards their legal personality. These difficulties prevent smaller operators from becoming part of groups of operators. In third countries, the reorganisation of the producers' activities can also result in difficulties in supplying the Union with products originating from them, with the consequent risk of trade disruptions. The requirements relating to the annual turnover of the members of the groups of operators should therefore be abolished. In addition, the requirement relating to the maximum eligible surface areas of members' holdings should be revised upwards in order to allow the integration into groups of operators of smaller operators.

Regulation (EU) 2018/848 does not lay down any specific conversion period or a minimum age at slaughter for quails, hindering their production. It is therefore appropriate to lay down such rules. In the Member States where organic quails are currently raised for meat production, they are slaughtered from 42 days of age, with a conversion period of five weeks. This corresponds to one week less than the minimum age of slaughter for these species. Hence, the current period of conversion of 10 weeks for poultry for meat production is not appropriate for quails and should be shortened taking into account their age at slaughter. It is therefore appropriate to set a minimum age of 42 days at slaughter and a conversion period of five weeks for quails for meat production.

Regulation (EU) 2018/848 lays down rules on veterinary treatments. Those rules provide that, for terrestrial animals, the withdrawal period after the use of chemically synthesised allopathic medicinal products as defined in Regulation (EU) 2019/6 of the European Parliament and of the Council is twice the normal withdrawal period and with a minimum duration of 48 hours. This means that, even if the applicable normal withdrawal period of the veterinary medicinal product is zero days, the withdrawal period must be a minimum of 48 hours. For aquaculture, those rules provide that the withdrawal period after the use of veterinary medicinal products is twice the normal withdrawal period, or a minimum duration of 48 hours if no period is

specified. To avoid a burden for the production of terrestrial animals, particularly in cases where the withdrawal period specified in the veterinary medicinal product is zero days, the provisions for terrestrial animals and aquaculture should therefore be aligned.

Regulation (EU) 2018/848 requires that poultry must be provided with continuous daytime open air access from as early an age as practically possible. Such a requirement can put at risk the safety of young, unfeathered birds in the period of their production cycle when they need, among other elements, stable temperatures to develop their feeding and drinking behaviours, their immunisation against infections, and shelter from any predators. Those requirements should therefore be amended to require access to open air areas only to birds that are sufficiently feathered to regulate their body temperature when exposed to outdoor climatic conditions.

Regulation (EU) 2018/848 provides that the total usable surface area for fattening poultry in poultry houses of any production unit must not exceed 1 600 m<sup>2</sup>. This limits the further development of organic fattening poultry production by limiting the size of any fattening poultry house in an organic production unit without bringing additional benefit to animal welfare and the environment. The maximum usable surface area for fattening poultry should therefore be defined at the level of the poultry houses.

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Regulation (EU) 2018/848 as regards certain production, labelling and certification rules and certain rules on trade with third countries**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,  
 Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) thereof,  
 Having regard to the proposal from the European Commission,  
 After transmission of the draft legislative act to the national parliaments,  
 Having regard to the opinion of the European Economic and Social Committee<sup>8</sup>,  
 Having regard to the opinion of the Committee of the Regions<sup>9</sup>,  
 Acting in accordance with the ordinary legislative procedure,  
 Whereas:

- (1) Regulation (EU) 2018/848 lays down provisions for the authorisation of products and substances for use in organic production. In particular, the Commission may authorise products for cleaning and disinfection in processing and storage facilities for use in organic production and include them in restrictive lists. However, there are a number of challenges associated with the establishment of such lists, as confirmed by several reports from the Expert Group for Technical Advice on Organic Production (EGTOP)<sup>10</sup>. First, there are a large number of products and substances for cleaning and disinfection of processing and storage facilities currently available on the Union market. Second, the processing and storage of organic products takes place in many different types of establishments and involves the use of a wide range of equipment, machinery and buildings. Third, the equipment and machinery for processing and storage must be cleaned and disinfected in accordance with the manufacturers' specifications in order to ensure its appropriate maintenance and operation. With a

<sup>8</sup> OJ C, ...

<sup>9</sup> OJ C, ...

<sup>10</sup> EGTOP, 'Final report on the criteria for evaluation of products for cleaning and disinfection', 8 December 2021, [https://agriculture.ec.europa.eu/document/download/2cd40421-9a7e-432c-9818-947cc97358c4\\_en?filename=egtop-report-on-criteria-cleaning-and-disinfection\\_en.pdf](https://agriculture.ec.europa.eu/document/download/2cd40421-9a7e-432c-9818-947cc97358c4_en?filename=egtop-report-on-criteria-cleaning-and-disinfection_en.pdf); EGTOP, 'Final report on cleaning and disinfection (III)', 14 April 2025, [https://agriculture.ec.europa.eu/document/download/bc0480a6-d269-468b-97df-3da3216f0d4d\\_en?filename=final-report-egtop-on-cleaning-disinfectant-iii\\_en.pdf](https://agriculture.ec.europa.eu/document/download/bc0480a6-d269-468b-97df-3da3216f0d4d_en?filename=final-report-egtop-on-cleaning-disinfectant-iii_en.pdf); EGTOP, 'Final report on cleaning and disinfection (IV)', 6 November 2025, [https://agriculture.ec.europa.eu/farming/organic-farming/co-operation-and-expert-advice/egtop-reports\\_en](https://agriculture.ec.europa.eu/farming/organic-farming/co-operation-and-expert-advice/egtop-reports_en)

view to allowing organic operators to use products and substances for cleaning and disinfectants available on the market, the requirement for the Commission to authorise products for cleaning and disinfection in processing and storage facilities for use in organic production and include them in restrictive lists should be deleted.

- (2) Regulation (EU) 2018/848 lays down rules for the import of products from third countries for the purpose of placing such products on the Union market as organic or in-conversion products. Under those rules, organic products can have access to the Union market where they comply with the Union rules on organic production or where they come from third countries whose organic production and control systems have been recognised as equivalent to those of the Union, either through an international agreement between the Union and those third countries or where the third countries were recognised for the purpose of equivalence under Regulation (EC) No 834/2007.
- (3) In Case C-240/23 *Herbaria Kräuterparadies II*, the Court of Justice of the European Union (ECJ) ruled that Regulation (EU) 2018/848 must be interpreted as meaning that a product imported from a third country whose organic production and control systems have been recognised as equivalent to those of the Union, either through an international agreement between the Union and those third countries or where the third countries were recognised for the purpose of equivalence under Regulation (EC) No 834/2007, may not have on its labelling either the organic production logo of the European Union or, in principle, terms referring to organic production. The ECJ further ruled that, in order to ensure the effectiveness of Regulation (EU) 2018/848, as well as to preserve the powers which that Regulation confers on the Commission, the use of the organic production logo of the third country from which such product comes should be permitted on the product, even where that logo contains terms identical to those referring to organic production, within the meaning of Article 30(1) of that Regulation (EU) 2018/848 and Annex IV thereto.
- (4) The use for a product imported from a third country whose organic production and control systems has been recognised as equivalent to those of the Union of the organic production logo of a third country is not liable to harm fair competition within the internal market in organic products or to give rise to ambiguity that may mislead consumers. This is because such a logo neither places the product concerned on the same level as Union organic products from the point of view of competition or is it liable to give the impression that the product concerned complies with all the requirements laid down by Regulation (EU) 2018/848.
- (5) Terms referring to organic production, including their derivatives and diminutives, are used both in the Union and in third countries to suggest to the purchaser that the product and its ingredients have been produced in accordance with applicable organic production methods. This is also the case in the Codex Alimentarius guidelines CAC/GL 32<sup>11</sup>, where terms referring to organic production methods such as ‘organic’, ‘biological’, ‘ecological’ or words of similar intent including diminutives are used to suggest to the purchaser that the product or its ingredients were produced in accordance with organic production methods. In addition, certain organic production rules in third countries require terms referring to organic production to be used for products and their ingredients that have been produced in accordance with applicable organic production methods.

---

<sup>11</sup> Guidelines for the production, processing, labelling and marketing of organically produced foods GL 32–1999: [https://www.fao.org/input/download/standards/360/cxg\\_032e.pdf](https://www.fao.org/input/download/standards/360/cxg_032e.pdf)

- (6) Not every third country whose organic production and control systems have been recognised as equivalent to those of the Union has its own organic production logo. Consequently, if products from such third countries could not bear terms referring to organic production, this would deprive operators in those third countries of the possibility to indicate the organic status of such products and to suggest to purchasers in the Union that those products originate from organic production and are produced in accordance with organic production methods in their countries of origin. This would also be difficult to reconcile with the Codex Alimentarius guidelines CAC/GL 32 because it would not be possible to refer to organic production methods in the labelling of such products despite them meeting all the corresponding conditions set out in those guidelines.
- (7) In order to ensure the effectiveness of Regulation (EU) 2018/848, as well as to preserve the powers which that Regulation confers on the Commission, products imported from third countries whose organic production and control systems have been recognised as equivalent to those of the Union, either through an international agreement between the Union and those third countries or where the third countries were recognised for the purpose of equivalence under Regulation (EC) No 834/2007, which have access to the Union market as organic products, should therefore be allowed to bear terms referring to organic production.
- (8) The recognition of the organic production and control systems of a third country as equivalent to those of the Union means that such a system has been assessed as meeting the same objectives and principles as those of the Union by applying rules which ensure the same level of assurance of conformity, even if that is achieved through different means.
- (9) Differences between the rules applied in organic production and control systems of third countries recognised as equivalent and those applied in the Union are intrinsic to the equivalence regime. The assessment of equivalence by the Commission has shown that while some of those differences are limited in scope, other differences involve rules of organic production which play an important role in the structure of organic production in the Union and contribute to achieving the objective of satisfying consumer expectations as regards organic products whilst ensuring fair competition within the internal market between products that fully comply with Union production and control rules and those that comply with rules equivalent to those Union rules. Those rules include living soil, animal welfare standards and processing of food using minimum artificial inputs.
- (10) A Eurobarometer survey conducted in June and July 2024 and entitled ‘Europeans, Agriculture and the CAP’ indicated that the organic production logo of the European Union is the food product logo of which Europeans are the most aware. It is essential to both consumers and producers because it makes it easier for consumers to identify organic products and helps producers to market them across the Union.
- (11) In order to ensure fair competition within the internal market between products that fully comply with Union production and control rules and those that comply with rules equivalent to those Union rules, and in order to respond to consumer expectations that products imported from third countries whose organic production and control systems have been recognised as equivalent to those of the Union meet standards as high as those of the Union, the use of the organic production logo of the European Union should be allowed in the labelling, presentation and advertising of products imported

- from those third countries, provided that, in addition to those equivalent rules, those products comply with certain additional production and control requirements.
- (12) In order to preserve the effectiveness of Regulation (EU) 2018/848 as regards trade with third countries, such additional requirements should correspond to production and control rules that play an important role in the structure of organic production in the EU and contribute to achieving the objective of satisfying consumer expectations as regards organic products whilst ensuring fair competition within the internal market.
  - (13) Where there are changes to the production and control rules in the Union or in third countries whose organic production and control systems have been recognised as equivalent to those of the Union, the power to adopt certain acts should be delegated to the Commission in respect of adding or amending the additional production and control requirements with which products imported from those third countries must comply in order to use the organic production logo of the European Union.
  - (14) Operators in the Union that produce organic food and feed rely on the use of ingredients imported from third countries whose organic production and control systems have been recognised as equivalent to those of the Union. Such ingredients are used in variable proportions during the processing of organic products in the Union and are necessary for a large variety of organic products processed in the Union. Processing operations in the Union, when using those ingredients, take place in compliance with the production rules set out in Regulation (EU) 2018/848. The use of the organic production logo of the European Union should therefore be allowed by products processed in the Union and that contain organic ingredients either produced in accordance with this Regulation or imported from third countries whose organic production and control systems have been recognised as equivalent to those of the Union and where those ingredients account for 5% or less of the agricultural ingredients of the product (by weight for food and in general for feed). Where those ingredients account for more than 5% of the agricultural ingredients of the product (by weight for food and in general for feed), and in order to ensure a fair competition within the internal market between processed products containing ingredients that fully comply with Union production and control rules and those that comply with rules equivalent to those Union rules, and in order to respond to consumer expectations in relation to the use of the organic production logo of the European Union, that logo should be allowed in the labelling, presentation and advertising of processed products containing ingredients imported from those third countries, provided that, in addition to those equivalent rules, those ingredients comply with certain additional production and control requirements.
  - (15) Regulation (EU) 2018/848 provides that the use of the organic production logo of the European Union is obligatory for all organic prepacked food produced within the Union. It is therefore necessary to exclude from that obligation prepacked food produced within the Union with ingredients imported from third countries whose organic production and control systems have been recognised as equivalent to those of the Union and where those ingredients account for more than 5% of the agricultural ingredients of the product by weight and do not comply with certain additional production and control requirements.
  - (16) Regulation (EU) 2018/848 lays down provisions on the conditions under which Member States can exempt smaller operators from the obligation to be in the possession of a certificate pursuant to Article 35(1) of that Regulation. The increasing costs experienced by smaller operators since the entry into application of Regulation

(EU) 2018/848 have increased their turnover in relation to unpacked organic products other than feed. This has created a barrier to the fulfilment of the conditions relating to their turnover in order to be exempted from the obligation of being in possession of a certificate pursuant to Article 35(1). Such a barrier in turn results in increased costs due to that obligation. The conditions relating to the annual turnover under which Member States can exempt smaller operators from being in possession of a certificate pursuant to Article 35(1) of that Regulation should therefore be abolished. In addition, the condition relating to annual sales should be revised upwards in order not to hinder smaller operators from being exempted from the obligation of being in possession of a certificate pursuant to Article 35(1) of that Regulation.

- (17) Regulation (EU) 2018/848 lays down provisions on the composition of groups of operators in the Union and in third countries. Evidence in relation to the implementation of those provisions shows significant difficulties in setting up groups of operators that fulfil requirements as regards the composition of members, in particular the annual turnover, and as regards their legal personality. Such difficulties include administrative costs and the need to reorganise the economic activities of groups of producers that are currently in cooperative associations, operator cooperatives, associations, federations or organisations. Such difficulties prevent smaller operators from becoming part of groups of operators, since provisions in place do not appropriately reflect the needs and resource capacity of small farmers and operators, at the disadvantage of the development of organic farming both in the Union and in third countries. In third countries, the reorganisation of the producers' activities can also result in difficulties in supplying the Union with products originating from them, with the consequent risk of trade disruptions. The requirements relating to the annual turnover of the members of the groups of operators should therefore be abolished. In addition, the requirement relating to the maximum eligible surface areas of members' holdings should be revised upwards in order to allow the integration into groups of operators of smaller operators.
- (18) The recognition of third countries whose organic production and control systems have been recognised as equivalent to those of the Union will expire on 31 December 2026. On 28 June 2021, the Council authorised the Commission to open negotiations with the eleven third countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007 with a view to concluding international agreements with them on trade in organic products. On that basis, the Commission has been conducting technical exchanges with these third countries. Those exchanges show different levels of progress, due to the diversity of legal and regulatory frameworks and complexities linked to varying consumer perceptions of organic production from one organic production system to the other. It is therefore necessary and urgent for those third countries to continue to be recognised until 31 December 2036 to avoid disruptions in the trade of organic products.
- (19) Regulation (EU) 2018/848 lays down a conversion period for poultry for meat production and a minimum age at slaughter, in cases where slow-growing poultry strains are not used. Such provisions do not lay down any specific conversion period or a minimum age at slaughter for quails. In the Member States where organic quails are raised for meat production, their production cycle is shorter than the one applicable to other species of poultry for meat production, since they are slaughtered from 42 days of age. The conversion period should be five weeks. This corresponds to one week less than the minimum age of slaughter for these species. Hence, the current period of conversion of 10 weeks for poultry for meat production is not appropriate for

quails and should be shortened taking into account their age at slaughter. It is therefore appropriate to set a conversion period of five weeks for quails for meat production and a minimum age of 42 days at slaughter.

- (20) Regulation (EU) 2018/848 lays down rules on veterinary treatments. Those rules provide that, for terrestrial animals, the withdrawal period after the use of chemically synthesised allopathic medicinal products as defined in Regulation (EU) 2019/6 of the European Parliament and of the Council<sup>12</sup> is twice the normal withdrawal period and with a minimum duration of 48 hours. This means that, even if the applicable normal withdrawal period of the veterinary medicinal product is zero days, the withdrawal period must be a minimum of 48 hours. For aquaculture, those rules provide that the withdrawal period after the use of allopathic veterinary medicinal products must be twice that of an authorised veterinary medicinal product, or a minimum of 48 hours if no period is specified. To avoid a burden for the production of terrestrial animals, particularly in cases where the withdrawal period specified in the veterinary medicinal product is zero days, the provisions for terrestrial animals and aquaculture should therefore be aligned.
- (21) Regulation (EU) 2018/848 lays down rules on housing and husbandry practices for poultry, including that poultry must be provided with continuous daytime open air access from as early an age as practically possible. However, such rule can put at risk the safety of young, unfeathered birds in the period of their production cycle when they need, among other elements, stable temperatures to develop their feeding and drinking behaviours, their immunisation against infections, and shelter from any predators. That rule should therefore be amended to require access to open air areas only to birds that are sufficiently feathered to regulate their body temperature when exposed to outdoor climatic conditions.
- (22) Regulation (EU) 2018/848 provides that the total usable surface area for fattening poultry in poultry houses of any production unit must not exceed 1 600 m<sup>2</sup>. This limits the further development of organic fattening poultry production by limiting the size of any fattening poultry house in an organic production unit without bringing additional benefit to animal welfare and the environment. Regulation (EU) 2018/848 should therefore be amended to define the maximum usable surface area for fattening poultry at the level of the poultry houses.
- (23) Since the objectives of this Regulation, in particular fair competition and the proper functioning of the internal market in organic products, as well as ensuring consumer confidence in those products and in the organic production logo of the European Union, cannot be sufficiently achieved by the Member States but can rather, by reason of the required harmonisation of the rules on organic production, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (24) Regulation (EU) 2018/848 should therefore be amended accordingly.

---

<sup>12</sup> Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43, ELI: <http://data.europa.eu/eli/reg/2019/6/oj>).

- (25) In view of the need to avoid unnecessary disruptions in the trade of organic products and to ensure a smooth transition to the scheme of recognition of third countries through international agreements, as well as to remove unnecessary burdens on organic operators, this Regulation should enter into force, as a matter of urgency, on the day following that of its publication in the *Official Journal of the European Union*,

HAVE ADOPTED THIS REGULATION:

#### *Article 1*

Regulation (EU) 2018/848 is amended as follows:

- (1) in Article 24(1), point (g) is deleted;
- (2) Article 30 is amended as follows:
  - (a) paragraph 1 is replaced by the following:

‘1. For the purposes of this Regulation, a product shall bear terms referring to organic production where, in the labelling, advertising material or commercial documents, such a product, its ingredients or feed materials used for its production are described in terms suggesting to the purchaser that the product, ingredients or feed materials have been produced in accordance with this Regulation. In particular, the terms listed in Annex IV and their derivatives and diminutives, such as ‘bio’ and ‘eco’, whether alone or in combination, may be used throughout the Union and in any language listed in that Annex for the labelling and advertising of products referred to in Article 2(1) which comply with this Regulation or are imported from a third country under the conditions laid down in Article 45(1), points (b)(ii) or (iii), for the purpose of placing such products on the market within the Union as organic products.’;
  - (b) in paragraph 2, the first subparagraph is replaced by the following:

‘For the products referred to in Article 2(1), the terms referred to in paragraph 1 of this Article shall not be used anywhere in the Union, in any language listed in Annex IV, for the labelling, advertising material or commercial documents of a product which does not comply with this Regulation or is not imported from a third country under the conditions laid down in Article 45, points (b)(ii) or (iii), for the purposes of placing that product on the market within the Union as an organic product.’;
- (3) in Article 32(1), point (b) is replaced by the following:

‘(b) In the case of prepacked food, the organic production logo of the European Union referred in Article 33 shall also appear on the packaging, except in the following cases:

  - in the case referred to in Article 30(3);
  - in the cases referred to in points (b) and (c) of Article 30(5);
  - in the cases where the processed food as referred to in point (a) of Article 30(5) is made with ingredients imported in accordance with Article 45(1), points (b)(ii) or (iii) and where such ingredients account for more than 5% of the organic agricultural ingredients of the product by weight of the processed food and do not comply with the requirements set out in Annex VII.’;
- (4) Article 33 is replaced by the following:

### **Organic production logo of the European Union**

1. The organic production logo of the European Union may be used in the following cases:
  - (a) in the labelling, presentation and advertising of products which are produced in accordance with the rules laid down in Chapters II, III and IV;
  - (b) in the labelling, presentation and advertising of products that are imported in accordance with of Article 45(1), points (b)(ii) or (iii), and that comply with the requirements set out in Annex VII;
  - (c) for processed food referred to in Article 30(5), point (a), and processed feed referred to in Article 30(6), with ingredients that are imported in accordance with Article 45(1), points (b)(ii) or (iii), provided that those ingredients comply with the requirements set out in Annex VII or represent less than 5% of the organic agricultural ingredients of the product by weight for processed food or less than 5% of the organic ingredients of agricultural origin that are contained in the processed feed;
  - (d) for information and educational purposes related to the existence and advertising of the logo itself, provided that such use is not liable to mislead the consumer as regards the organic production of specific products, and provided that the logo is reproduced in accordance with the rules set out in Annex V. In such case, the requirements of Article 32(2) and point 1.7 of Annex V shall not apply.

The organic production logo of the European Union shall not be used for processed food referred to in Article 30(5), points (b) and (c), and for in-conversion products as referred to in Article 30(3).
2. Except where used in accordance with paragraph 1, point (d), the organic production logo of the European Union is an official attestation in accordance with Articles 86 and 91 of Regulation (EU) 2017/625.
3. The use of the organic production logo of the European Union shall be optional for products imported from third countries. Where that logo appears in the labelling of such products in accordance with paragraph 1, the indication referred to in Article 32(2) shall also appear in the labelling.
4. The organic production logo of the European Union shall follow the model set out in Annex V, and shall comply with the rules set out in that Annex.
5. National logos and private logos may be used in the labelling, presentation and advertising of products which comply with this Regulation.
6. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending Annex V as regards the organic production logo of the European Union and the rules relating thereto.
7. The Commission is empowered to adopt delegated acts in accordance with Article 54 amending Annex VII on the use of the organic production logo of the European Union for products imported in accordance Article 45(1), with points (b)(ii) or (iii), by adding requirements that need to be met to fulfil consumers' expectations and maintain fair competition on the Union market of organic products, or by amending those added requirements, as regards in particular the use of sustainable systems for

plant production, of livestock production systems ensuring animal welfare and sustainable nutrition, of food processing methods using minimum artificial inputs, while at the same time taking into account third countries' specificities for products not grown or processed in the Union.';

(5) in Article 35(8), the first subparagraph is replaced by the following:

'Member States may exempt from the obligation to be in the possession of a certificate referred to in paragraph 2 operators that sell unpacked organic products other than feed directly to the final consumer, provided that those operators do not produce, prepare, store other than in connection with the point of sale, or import such products from a third country, or subcontract such activities to a third party, and provided that such sales do not exceed 10 000 kg per year.';

(6) in Article 36, paragraph 1 is amended as follows:

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

'(b) only be composed of members who each have holdings of maximum:

— (i) 10 hectares,

— (ii) one hectare, in the case of greenhouses, or

— (iii) 30 hectares, exclusively in the case of permanent grassland;';

(b) point (d) is replaced by the following:

'(d) have legal personality or be part of a farmer cooperative association, operator cooperative, association, federation or organisation that has legal personality;';

(7) in Article 48(1), second subparagraph, the date '31 December 2026' is replaced by '31 December 2036'

(8) Annex II is amended as follows:

(a) Part II is amended as follows:

(a) in point 1.2.2., points (c) and (d) are replaced by the following:

'(c) 10 weeks for poultry for meat production, except for Peking ducks and quails, brought in before they are three days old;

(d) seven weeks for Peking ducks and five weeks for quails brought in before they are three days old;';

(b) point 1.5.2.5. is replaced by the following:

'1.5.2.5. The withdrawal period, as defined in Article 4, point (34), of Regulation (EU) 2019/6 of the European Parliament and of the Council\*, of a chemically synthesized allopathic veterinary medicinal product, including of an antimicrobial veterinary medicinal product, shall be twice the withdrawal period referred to in:

(a) the product information for veterinary medicinal products used within the terms of their marketing authorisation; or

(b) Article 115 of that Regulation, where a medicinal product is used outside of the terms of the marketing authorisation in accordance with Article 113 of that Regulation.'

---

\* Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43, ELI: <http://data.europa.eu/eli/reg/2019/6/oj>).’;

- (c) in point 1.9.4.1, in the third subparagraph, the following point is added:
  - ‘(j) 42 days for quails.’;
- (d) point 1.9.4.4. is amended as follows:
  - (i) point (e) is replaced by the following:
    - ‘(e) continuous daytime open air access shall be provided from as early an age as birds are sufficiently feathered to regulate their body temperature when exposed to outdoor climatic conditions and whenever physiological and physical conditions allow, except where temporary restrictions have been imposed pursuant to Union legislation;’;
  - (ii) point (m) is replaced by the following:
    - ‘(m) the total usable surface area for fattening poultry in poultry houses shall not exceed 1 600 m<sup>2</sup> in any poultry house;’;
- (b) in Part III, point 3.1.4.2(f) is replaced by the following:
  - ‘The withdrawal period, as defined in Article 4, point (34), of Regulation (EU) 2019/6, of an allopathic veterinary medicinal product shall be twice the withdrawal period referred to in:
    - (a) the product information for veterinary medicinal products used within the terms of their marketing authorisation; or
    - (b) Article 115 of that Regulation, where a medicinal product is used outside the terms of the marketing authorisation in accordance with Article 114 of that Regulation.’;
- (c) in part IV, point 2.2.3. is deleted;
- (d) in part V, point 2.4. is deleted;
- (e) in part VII, point 1.4. is deleted;
- (f) in Annex III, point 7.5. is deleted;
- (g) The following Annex is added:
  - ‘ANNEX VII
  - Requirements referred to in Article 32(1), point (b) and Article 33(1), points (b) and (c):
    - (1) point 1.2 of Part I of Annex II;
    - (2) point 1.7.5 of Part II of Annex II;
    - (3) point 1.7.11 of Part II of Annex II;
    - (4) point 2.2.2(f) of Part IV of Annex II’.

*Article 2*

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

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

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*