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Subject: EUROPEAN UNION COMMON POSITION
- Chapter 12: Food safety, veterinary and phytosanitary policy

EUROPEAN UNION COMMON POSITION

Chapter 12: Food safety, veterinary and phytosanitary policy

This position of the European Union is based on its general position for the Accession Conference with Montenegro (AD 23/12 CONF-ME 2) and is subject to the negotiating principles endorsed therein, in particular:

– any view expressed by either party on a chapter of the negotiations will in no way prejudge the position which may be taken on other chapters;

– agreements - even partial agreements - reached during the negotiations on chapters to be examined successively may not be considered as final until an overall agreement has been established;

– as well as the requirements set out in points 24, 28, 41 and 44 of the Negotiating Framework.

The EU underlines that Montenegro shall continue the process of alignment with the EU *acquis,* noting that additional *acquis* may enter into force before accession or that relevant EU legislation might be updated, to ensure its effective implementation and enforcement, and develop already before accession, policies and instruments as close as possible to those of the EU.

The EU notes that Montenegro, in its negotiating position AD 4/16 REV1 CONF-ME 3 and its AD 59/26 CONF-ME 23, accepts the *acquis* under Chapter 12 as in force on 30 June 2026, and that it declares that it will be ready to implement it by the date of its accession to the European Union, except for the areas where it requested transitional periods:

PUBLIC

- To be exempted until 31 August 2030 from the application of the provisions on structural requirements of certain establishments in the sectors of meat, milk, fish and eggs as set out in Regulations (EC) No 852/2004 and No 853/2004.

- To be exempted until 31 December 2030 from the application of the provisions on collection and processing of raw milk that does not fully comply with the requirements laid down in Regulation (EC) No 853/2004.

As an overall response to Montenegro's requests, the EU recalls its general negotiating position that transitional measures are exceptional, limited in time and scope, and accompanied by a plan with clearly defined stages for the application of the *acquis*. They must not involve amendments to the rules or policies of the EU, disrupt their proper functioning, or lead to significant distortion of competition.

After a careful re-examination and taking into account the measures underpinning the regulatory and procedural framework necessary for the consistent implementation and enforcement of EU food safety requirements in Montenegro, the EU considers Montenegro’s requests acceptable, subject to the conditions and monitoring process prescribed below.

Moreover, the EU considers that the Act of Accession should provide for the necessary legal basis to adopt transitional measures where these are necessary to facilitate the transition from the existing regime in Montenegro to that resulting from the application of Union veterinary, phytosanitary and food safety rules. Such measures shall be adopted by the Commission in accordance with the relevant procedure as determined in the applicable legislation. It should be possible to take such measures during a period of three years following the date of accession and the application thereof shall be limited to that period.

PUBLIC

General Food Safety

The EU welcomes the adoption of a new Food Safety Law in April 2026. The EU takes note that this legislation further aligns Montenegro with Regulation (EC) No 178/2002 by setting the principles and requirements covering all stages of production and distribution of food/feed, traceability of food and feed, and the obligations and responsibilities of food and feed business operators. The EU highlights that Montenegro shall further align with and implement the EU secondary legislation in this area.

Concerning **official controls**, the EU welcomes the adoption of the Law on Official Controls aligning with Regulation (EU) 2017/625 on official controls and preparing legislative alignment in relation with EU imports rules in May 2026. The EU takes note of Montenegro's plans to fully align in this area by Q4 2027. It also takes note of Montenegro's progress with regards to the set-up and development of the relevant administrative capacity and infrastructure for official controls by the competent authorities in accordance with the *acquis.* This includes their funding, along the entire food safety chain, and upon entry from other countries, to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products. The EU invites Montenegro to provide regular updates on the subject until accession, including on progress with regard to the standardization of official control procedures, in particular strengthening administrative capacities, inspection services, laboratory support and border controls.

PUBLIC

The EU takes note of Montenegro's decision to construct and upgrade six border control posts, namely Airport Golubovci, Božaj, Port Bar, Kula, Dobrakovo and Ilino Brdo, planned under the Roadmap for the Upgrading and Construction of Border Control Posts. The EU urges Montenegro to complete the construction, upgrading and equipping of its six border control posts at the points of entry, so that they are fully operational upon accession and to provide regular updates on the progress until the border control posts are operational, including contingency plans in case of delays. In particular, the EU will monitor progress of Montenegro in construction and equipment of border control post for live animals, where animal welfare checks are required to be carried out. The EU takes note of the contingency plans provided in the update of the above-mentioned roadmap in June 2026, which aim to address potential delays in the delivery of operational border control posts. The EU underlines that the border control posts must be fully compliant for entry of animals and goods by the date of accession. The EU underlines that Montenegro shall provide regular updates on the construction, equipping and operational status of the border control posts, until full operationality of the six BCPs, including at least one report by July 2027 and one by December 2027. The reports shall assess the operational status of the six BCPs, including any identified delays, and update the contingency scenarios that could be implemented.

The EU underlines that Montenegro needs to ensure that all relevant functions of the TRACES information system are used in all border control posts and by all the inspectors in line with EU requirements.

PUBLIC

Concerning **laboratories**, the EU takes note of the progress made by Montenegro on planning the designation of a network of national reference laboratories (NRL) for official controls for each EU reference laboratory. The EU takes note of Montenegro's intention to designate NRLs by December 2026 and to designate by June 2027 the NRLs that will be located in an EU Member State. The EU takes note of Montenegro's ongoing investments in the upgrading of laboratory capacities through the modernisation of equipment and the development of accredited methods for its laboratory network. The EU acknowledges the very detailed information as regards the laboratory capacity, the planning on the designation of NRLs, existing gaps and solutions to address these gaps, provided in the revised NRL Roadmap completed in July 2026. The EU notes that Montenegro will need to continue their efforts to have their network of National Reference Laboratories for all relevant domains in animal health, plant health and feed and food safety operating by the date of accession. The EU urges Montenegro to finalise the National Reference Phytosanitary Laboratory. The EU also underlines the importance of ensuring the timely accreditation and effective operation of the National Reference Phytosanitary Laboratory. The EU expects Montenegro to provide regular updates until accession, including at least one update report by the end of Q2 2027 and another one by the end of Q4 2027, regarding (i) the designated NRLs, (ii) the actions identified in the roadmap that have been implemented and to be implemented, which aim to address the identified gaps and (iii) the construction, equipping and operational status of the National Reference Phytosanitary Laboratory.

The EU stresses the critical need for Montenegro to ensure ISO/IEC 17025 accreditation for all laboratories performing official controls, ensuring full equivalence with EU requirements and to formally designate the complete network of Official Laboratories and National Reference Laboratories as stipulated under Regulation (EU) 2017/625, including clear mandates, defined competences, and operational coordination mechanisms. The EU expects Montenegro to provide regular updates on the subject.

PUBLIC

The EU acknowledges Montenegro's progress in engaging technical assistance and cooperating with EU Member States, to ensure comprehensive coverage of analyses under the EU *acquis*. The EU expects Montenegro to continue the process of alignment with the *acquis* and its effective implementation in this area.

The EU takes note of the information provided by Montenegro about control rules and specific control rules for animal products. The EU underlines the importance for Montenegro to strengthen its administrative capacity to conduct controls in compliance with the *acquis* in this field, as it is crucial that the control system is fully operational by the date of accession.

The EU takes note of the establishment of a framework for strengthening administrative capacities and the official control system and calls on Montenegro to address any remaining shortcomings in the animal welfare area related to efficient and risk-based controls (at farm, during transport and at slaughter).

Concerning **institutional framework**, the EU takes positive note of Montenegro's adoption, in December 2025, of the Rulebook on Internal Organization and Systematization of the Administration for Food Safety, Veterinary and Phytosanitary Affairs, based on which, Montenegro adopted the revised Action Plan for strengthening the administrative capacities in this area on 23 July 2026. The EU encourages Montenegro to regularly report on the implementation of the Action Plan, which provides for the recruitment of 147 officials by 2030, and in particular 26 officials in 2026, 31 officials in 2027, and 30 officials annually in each of the following three years. The EU calls on Montenegro to closely follow the recommendations by the European Commission regarding the impartiality and conflict of interest rules. To ensure compliance with EU requirements on these core principles, the EU expects the authorities to strengthen the relevant safeguards in both public administration and delegated services. The EU expects Montenegro to provide reports on the remaining human resources to be recruited and on alternative scenarios to address any shortcomings, twice a year until the end of the action plan on administrative capacity.

PUBLIC

Veterinary Policy

Concerning animal health, the EU welcomes Montenegro's adoption of the new Law on animal health in June 2026 aligning with Regulation (EU) 2016/429 and which represents the legal basis for further aligning with EU legislation under this framework. The EU takes note that the law will enter into force in 2027 and urges Montenegro to continue with legislative alignment and implementation of relevant animal health legislation under this and other frameworks while ensuring full compliance and effective implementation of the *acquis* in this animal health field upon accession.

The EU urges Montenegro to ensure effective implementation of Commission Delegated Regulation (EU) 2020/689, supplementing Regulation (EU) 2016/429, about rules on surveillance, eradication programmes and disease-free status for brucellosis and tuberculosis, which is fundamental for animal health domain, raw milk sector and in upgrading relevant establishments to meet EU hygiene requirements. The EU expects Montenegro to provide reports on the implementation on this subject, twice a year until the accession. In particular, the EU expects Montenegro to provide clear and verifiable evidence demonstrating that other official activities related to animal health are effectively implemented in practice and are capable of ensuring timely detection and effective response to animal health risks throughout the territory, including information on the competent authorities, the allocation of responsibilities, the procedures and resources foreseen for the implementation of official activities in this area.

The EU underlines the importance of achieving full compliance with and implementation of the *acquis* upon accession in the area of animal welfare, including at farm level, during transport and at the time of killing. This is essential to safeguard public confidence in food production, address EU citizens' expectations regarding high animal welfare standards, and ensure fair competition for current Member State producers within the internal market.

The EU takes note of Montenegro's training and capacity building plan for official controls in the area of animal welfare for the period 2026-2030. In addition, the EU urges Montenegro to advance on aligning with and start the implementation of the new Regulation on the welfare of dogs and cats and their traceability of 17 June 2026 which will become applicable from mid-2028.

The EU underlines that Montenegro is yet to align with Implementing Regulation (EU) 2023/372 on livestock vessels, official controls and exit points, as well as Delegated Regulation (EU) 2023/842 on official controls of animal welfare on livestock vessels and calls on Montenegro to align its legislation by Q4 2026 as planned. The EU notes that consistent implementation of animal welfare standards during transport, at farm level and at the time of slaughter remains an area for improvement. Efforts are needed on enforcement and efficient risk-based official controls related to animal welfare in that area, including ensuring sufficient and trained staff in charge of animal welfare. Therefore, the EU urges Montenegro to duly implement its Training and Capacity Building Plan for official controls in the area of animal welfare for the time period 2026-2030 to achieve a sufficient level of implementation by the date of accession. The EU invites Montenegro to provide reports on the effective implementation on this subject twice a year until the accession.

The EU takes note of the information provided by Montenegro and the progress in registration of relevant establishments and identification and registration of animals. The EU calls on Montenegro to urgently address any remaining shortcomings in the registration of establishments keeping animals, approval of certain establishments keeping animals and identification and registration of animals which are needed for controls at all levels, including disease management. The EU underlines the importance of achieving full compliance with the *acquis* in this field upon accession.

The EU takes note of the information provided by Montenegro regarding zootechnical legislation and underlines the importance of achieving full alignment with the *acquis* in this field, such as Regulation (EU) 2016/1012, upon Montenegro's accession to the EU.

The EU notes that the above measures **fulfil the requirement of the second and third closing benchmarks** as set out in the EU common position (AD 17/16 CONF-ME8/**16**) requiring Montenegro to demonstrate its capacity and capability to fully implement the *acquis* under this chapter upon its accession to the EU. The EU urges Montenegro to regularly report on the developments and steps undertaken as regards enforcement on official controls and underlines that Montenegro is expected to continue ensuring implementation in this area upon accession to the EU.

PUBLIC

Placing food, feed and animal-by product on the market

Concerning **biological safety**, the EU welcomes Montenegro's adoption, in February 2026, of the Law on management and handling of animal by-products. The EU also welcomes Montenegro's adoption of the Regulation on the hygiene of food in May 2026 and the planned adoption of the Regulation on Specific Hygiene Requirements for Food of Animal Origin in Q4 2026. The EU takes note of the information provided by Montenegro regarding food hygiene rules and the progress on assessment of the establishments producing food and feed of non-animal and animal origin. The EU takes note of the information provided by Montenegro concerning the specific rules for products of animal origin and the progress made in further aligning with the *acquis* in this field.

The EU takes note of the Plan for the Management of Animal By-products Not Intended for Human Consumption (Plan on ABPs), last updated in April 2026. According to the Plan on ABPs, Montenegro committed to establish a system for safe collection and disposal of animal by-products, compliant with EU rules, by the time of accession including the construction of burial sites, collection centres and transport of relevant animal by-products to neighbouring countries. In addition, Montenegro committed to construct a processing plant for certain animal by-products by 1 January 2031. The EU highlights that Montenegro shall continue its efforts to implement the Plan on ABPs, with particular attention to the remaining implementation issues concerning cooperation with other countries in the region on the possible export of certain ABPs from Montenegro. The EU expects Montenegro to provide reports on the implementation of the plan for the management of animal by-products before the accession and then provide reports on the construction of a processing plant at least twice a year until February 2031. The EU will closely monitor the progress on establishing the system for safe collection and disposal of animal by-products, including categorisation and monitoring of all food and by-products establishments. The EU also takes note of the actions undertaken by Montenegro to upgrade its establishments for products of animal origin. The EU takes note of the information provided by Montenegro and the progress achieved and will continue to monitor the progress of alignment in the area of animal by-products.

PUBLIC

The measures presented by Montenegro **fulfil the requirement of the first closing benchmark** as set out in the EU common position (AD 17/16 CONF-ME 8) requiring Montenegro to demonstrate its capacity and capability to fully implement the acquis under this chapter upon its accession to the EU. At the same time, the EU underlines the importance of addressing the identified shortcomings by the time of accession and calls on Montenegro to accelerate the process on upgrading its establishments.

The EU underlines that the application of flexibility measures under Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004 should not lead to unequal conditions of competition, as this could have an indirect impact on the proper functioning of the internal market. Such measures should remain proportionate and duly justified and should not be used to address structural deficiencies, delay necessary investments, or authorise establishments that do not comply with essential hygiene requirements.

Furthermore, Montenegro is reminded that, upon accession, any national technical rules adopted in this area would be subject to the notification procedure under Directive (EU) 2015/1535 (TRIS). This procedure ensures transparency and allows the EU and the Member States to assess whether draft national measures could create unjustified barriers to the internal market.

Concerning **food safety rules** and specific rules, the EU welcomes the adoption of Montenegro's regulation on food contact materials in April 2026 and takes note of Montenegro's plan to amend its legislation on food additives, enzymes, food supplements, novel food and flavouring by Q4 2026. Concerning contaminants, the EU welcomes the adoption of Montenegro's Regulation on maximum levels for contaminants in May 2026. The EU encourages Montenegro to continue the process of alignment with the *acquis* and its effective implementation and to ensure the necessary administrative and control capacity.

PUBLIC

The EU takes note of the information provided by Montenegro on food safety rules covering quick frozen foodstuffs and ionising radiation. The EU encourages Montenegro to continue the process of alignment with the *acquis* and its effective implementation and to ensure the necessary administrative and control capacity.

The EU takes note of the information provided by Montenegro on specific rules for feed covering feed additives, compound feedstuffs, feed materials, undesirable substances, feedstuffs intended for nutrition, certain products used in animal nutrition and medicated feed. The EU encourages Montenegro to continue the process of alignment with the *acquis* and its effective implementation to ensure the necessary administrative and control capacity.

Phytosanitary Policy

Concerning plant health and plant reproductive material, the EU welcomes the adoption of Montenegro's Law on plant health protection in March 2026, aligning the country with Regulation (EU) 2016/2031, which stands as the legal framework for establishing a plant health system. The EU encourages Montenegro to provide regular information on the legislative developments and urges Montenegro to continue the implementation of secondary and tertiary legislation, in particular in relation to the listing of quarantine pests and import requirements, the multiannual survey programmes and annual survey reports, to ensure early detection and eradication of EU quarantine pests, and a functioning plant passport system, to ensure the plants are moved in accordance with the applicable requirements in Montenegro.

The EU expects that Montenegro will complete the development of the new phytosanitary information system for recording, analysing and sharing data collected during official controls and surveillance by Q4 2026. The EU underlines that the phytosanitary information system should be fully operational and effectively used to support official controls and surveillance.

PUBLIC

In this regard, the EU notes Montenegro's plan to submit the multiannual survey programme from 2027-2037 by 31 October 2026 and to revise the relevant Rulebooks to remove any duplication existing with the Law on plant health protection in relation to contingency plans for specific pests and plant passports. The EU also stresses the importance of the timely submission, adoption and effective implementation of the multiannual survey programme for 2027–2037.

Concerning quality of seeds and other plant reproductive material, including forest reproductive material, the EU notes Montenegro's progress and measures to align and implement secondary and tertiary legislation in this area. It is of particular importance that Montenegro has a functioning system of certification and control of seeds and other plant reproductive material in place. The EU underlines that Montenegro must also be ready to apply the respective protocols for testing of new varieties, align with the EU rules on the procedures of variety registration, and have examination centres entrusted by the CPVO (Community Plant Varieties Office), or access to examination centres of other Member States, to carry out testing of varieties.

Moreover, in the sector of forest reproductive material, the EU expect Montenegro to have a functioning system of approval of basic material, and of certification of derived forest reproductive material to be marketed in accordance with the respective EU rules. In all those sectors, Montenegro must ensure an effective system of official supervision of professional operators. The EU takes note of the information provided by Montenegro regarding its membership to the International Union of the Protection of New Varieties of Plants (UPOV).

Concerning pesticides, the EU welcomes the adoption of the new Law on Plant Protection Products (PPP), in line with Regulation (EC) No 396/2005, in April 2026 and notes that there is no production of plant protection products in Montenegro. The EU urges Montenegro to improve its system for granting authorisations for plant protection products and/or mutual recognition of such authorisations granted by other EU Member States, in line with Regulation (EC) no 1107/2009, and for monitoring of pesticide residues**.** in food and feed. The EU also urges Montenegro to establish institutional capacities for the implementation of these EU systems in the form of a structure most appropriate for Montenegro by the date of accession.

PUBLIC

Concerning laboratories, the EU takes note of Montenegro's intention to designate national reference laboratories by December 2026 for NRLs located in the territory of Montenegro and by June 2027 for NRLs located in an EU Member State. The EU urges Montenegro to work with accredited laboratories for PPP formulation assessments, and to implement the recommendations of the Gap Analysis of CETI Laboratory Capacities in relation to Pesticide Residues and Plant Protection Product Formulations in Montenegro, in line with Regulation (EU) 2017/625.

The EU encourages Montenegro to ensure the continuity and further development of its policy framework on the sustainable use of plant protection products beyond the current National Action Plan covering the period 2021–2026, in line with Directive 2009/128/EC.

Concerning genetically modified organisms, the EU notes Montenegro's effort and urges the country to ensure that its administrative structures allow for the effective implementation of the system in practice. The EU underlines the need for Montenegro to ensure full alignment with the EU *acquis* on genetically modified organisms, including implementation and enforcement, by the date of accession, in particular administrative, institutional, technical and laboratory capacities to ensure its effective implementation. The EU notes Montenegro's plan to conclude agreements with national laboratories of EU Member States for GMO testing.

As for international phytosanitary agreements in areas falling under the exclusive competence of the Union, Montenegro shall take the necessary steps to ensure alignment with the Union position before accession.

PUBLIC

The EU takes note of Montenegro's request for a transitional period until 31 August 2030 for establishments in the meat, milk, eggs and fish sectors which will not be in compliance with structural requirements pursuant to Regulations (EC) No 852/2004 and No 853/2004 on the day of Montenegro's accession to the EU. The EU considers the requested transitional period acceptable, but underlines that during the transitional period, products derived from such establishments will not be placed on the market of other Member States and would only be placed on the market of Montenegro and on markets of third countries in accordance with Article 12 of Regulation (EC) No 178/2002. The EU further underlines that such a measure may only apply for structural requirements and establishments covered by Article 12 and such establishments would not be allowed to trade their products with other EU Member States. The transitional period must be limited up until 31 August 2030 and only apply to a clearly defined, limited number of establishments in need of additional time to finish their upgrading process. At the end of the transitional period, non-compliant establishments shall cease their activities. To ensure effective segregation and traceability, products from those establishments shall bear a specific identification mark, to be defined and implemented sufficiently in advance of accession.

PUBLIC

The EU takes note of Montenegro's request for a transitional period until 31 December 2030 for deliveries of raw milk not meeting the hygiene requirements laid down in Regulation (EC) No 853/2004. The EU considers the requested transitional period acceptable, but underlines that during the transitional period, products from such raw milk will not be placed on the market of other Member States and would only be placed on the market of Montenegro and on markets of third countries in accordance with Article 12 of Regulation (EC) No 178/2002. The EU underlines that compliance of establishments with the *acquis* is of fundamental importance to ensure the functioning of the internal market and to guarantee a high level of protection. During this period, milk originating from such non-compliant holdings shall be collected separately and used exclusively to produce dairy products whose placing on the market shall be restricted to the territory of Montenegro or the markets of third countries in accordance with Article 12 of Regulation (EC) No 178/2002. To ensure effective segregation and traceability, those products shall bear a specific identification mark, to be defined and implemented sufficiently in advance before accession. The EU recalls that Montenegro shall communicate in due time before accession the number of establishments concerned by both transitional periods. Additionally, the EU underlines that Montenegro shall communicate no later than one year before accession the traceability measures and identification marks for products concerned.

PUBLIC

The EU invites Montenegro to continue demonstrating progress in alignment with and implementation of the relevant EU *acquis*. Particularly, this objective can only be ensured once herds or holdings obtain officially disease-free status for bovine tuberculosis and brucellosis. Achieving such status therefore constitutes an essential and ultimate precondition for the placing on the market of raw milk, including in cases where non-compliant products are limited to the domestic market. Derogations, traditional practices, testing regimes or transitional arrangements cannot substitute this requirement. In this context, effective implementation of Commission Delegated Regulation (EU) 2020/689, supplementing Regulation (EU) 2016/429, about rules on surveillance, eradication programmes and disease-free status for brucellosis and tuberculosis, will be essential to ensure progress towards compliance with the EU *acquis*.

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In view of the above considerations, the EU notes that, at this stage, **this chapter does not require further negotiations**.

Monitoring of progress in the alignment with and implementation of the EU *acquis* will continue throughout the negotiations. The EU underlines that it will devote particular attention to monitoring all specific issues mentioned above with a view to ensuring Montenegro's administrative capacity, its ability to implement and enforce the *acquis* in this chapter and the completion of the legislative alignment. Particular consideration needs to be given to the links between the present chapter and other negotiation chapters. A final assessment of the conformity of Montenegro's legislation with the EU *acquis* and of its implementation capacity can only be made at a later stage of the negotiations. In addition to all the information the EU may require for the negotiations in this chapter, which is to be provided to the Conference, the EU invites Montenegro to provide regularly detailed written information to the Stabilisation and Association Council on progress in the implementation of the *acquis* and in the strengthening of its administrative capacity.

PUBLIC

In view of all the above considerations, the EU will, if necessary, return to this chapter at an appropriate moment.

The EU notes that Montenegro, in its negotiating position AD 4/16 REV1 CONF-ME 3 and its AD 59/26 CONF-ME 23, accepts the *acquis* under Chapter 12 as in force on 30 June 2026, and that it declares that it will be ready to implement it by the date of its accession to the European Union, except for the areas where it requested transitional periods.

Furthermore, the EU recalls that there may be new *acquis* between 30 June 2026 and the date of accession.

PUBLIC

ANNEX II

to the revised DCP on chapter 12

(Food safety, veterinary and phytosanitary policy)

Legal Annex

Act concerning the conditions of accession of the Republic of Montenegro and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community

PART [XXX]

TEMPORARY PROVISIONS

TITLE [XX] – OTHER PROVISIONS

Article [XX]

If transitional measures are necessary to facilitate the transition from the existing regime in Montenegro to that resulting from the application of the Union veterinary, phytosanitary and food safety rules, such measures shall be adopted by the Commission in accordance with the relevant procedure as determined in the applicable legislation. These measures shall be adopted within a period of three years from the date of accession, and their application shall be limited to that period.

PUBLIC

ANNEX [XX]

List referred to in Article [XX] of the Act of Accession: transitional measures

[X]. FOOD SAFETY, VETERINARY AND PHYTOSANITARY POLICY

I. ESTABLISHMENTS (MEAT, MILK, FISH AND EGGS)

32004 R 0852: Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

32004 R 0853: Regulation (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 (OJ L 139, 30.4.2004, p. 55).

1. Until 31 August 2030, under the conditions set out in paragraphs 3 to 6, the structural requirements laid down in the following shall not apply to establishments listed in accordance with paragraph 2 in the meat, milk, fish and eggs sectors in Montenegro:

   (a) European Parliament and Council Regulation (EC) No 852/2004:

   – Annex II, Chapter II;

   (b) European Parliament and Council Regulation (EC) No 853/2004:

   – Annex III, Section I, Chapters II and III,

   – Annex III, Section II, Chapters II and III,

PUBLIC

– Annex III, Section V, Chapter I;

– Annex III, Section VIII, Chapter III ;

– Annex III, Section IX, Chapters I and II;

– Annex III, Section X, Chapter I and II.

2. In good time before accession, the Commission shall establish the list of the establishments referred to in paragraph 1. That list shall be made public and shall include the name and address of each establishment.

3. Products originating from those establishments shall only be placed on the national market of Montenegro or on markets of third countries in accordance with relevant Union legislation or used for further processing in establishments in Montenegro also covered by paragraph 1, irrespective of the date of marketing.

4. Products from those establishments shall bear a different health or identification mark to that provided for in Article 5 of Regulation (EC) No 853/2004. A clear description of the different health or identification mark shall be communicated to the Commission no later than one year before the date of accession.

5. The competent authorities of Montenegro shall ensure that the health or identification marks referred to in paragraph 4 are used exclusively for the products for which they are intended and are protected against fraudulent or unauthorised use.

6. Paragraphs 3 and 4 also apply to all products originating from integrated meat, milk, fishery or eggs establishments where a part of the establishment is subject to paragraph 1.

PUBLIC

7. Montenegro shall continuously monitor the implementation of the national programme for upgrading establishments and shall provide the Commission with a bi-annual plan of progress in this respect. Montenegro shall ensure that an individual upgrading plan for each of these establishments with deadlines for the correction of the structural requirements is elaborated and made available to the Commission on request.

8. Montenegro shall ensure that any establishments which by the date of accession fail fully to comply with the food safety acquis of the Union, except where covered by the provisions of this transitional measure, terminate their activities.

9. The Commission may adopt detailed implementing rules to ensure the smooth operation of the above transitional regime in accordance with the procedure referred to in Article 14(2) of Regulation (EC) No 852/2004 and with Article 12(2) of Regulation (EC) No 853/2004 respectively.

II. PROCESSING OF NON-COMPLIANT MILK

32004 R 0853: Regulation (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 (OJ L 139, 30.4.2004, p. 55).

1. Dairy processing establishments in Montenegro may until 31 December 2030 receive deliveries of raw milk that do not comply with the requirements of Annex III, Section IX, Chapter I, Part III, point 3(a), of Regulation (EC) No 853/2004.

2. Until 31 December 2030, dairy processing establishments in Montenegro may continue to process both compliant and non-compliant milk on the same production line, provided that the compliant and non-compliant milk are kept segregated from the point of collection up to the final product stage, including at the holding through transport, reception, storage and processing, and that such processing is carried out in separate production runs after the processing of compliant milk, is segregated, and is subject to procedures ensuring that no cross-contamination occurs.

PUBLIC

3. Without prejudice to paragraph 1, dairy processing establishments shall comply with the Union requirements applicable to establishments, including the implementation of the Hazard Analysis and Critical Control Point (HACCP) principles referred to in Article 5 of Regulation (EC) No 852/2004, and shall demonstrate their capacity to comply with the following conditions, including by identifying the production line and the separate production runs used for the processing of non-compliant milk.

The operators of these establishments shall:

(a) ensure the effective segregation of compliant and non-compliant milk from collection up to the final product stage, including at the holding through transport, reception, storage, processing and distribution of the final products, including separate milk collection routes, separate storage and treatment of compliant and non-compliant milk, specific packaging and labelling of products derived from non-compliant milk, and separate storage of such products;

(b) establish procedures ensuring the traceability of raw materials and products, including the documentary recording of product movements and the accounting for, and reconciliation of, compliant and non-compliant raw milk with the categories and quantities of products produced;

(c) ensure that all non-compliant raw milk is subjected to a heat treatment of at least 71,7 °C for 15 seconds, or to another treatment achieving an equivalent level of safety;

(d) ensure that the health or identification marks referred to in paragraph 6 are used exclusively for the products for which they are intended and are protected against fraudulent or unauthorised use.

PUBLIC

4. The competent authorities of Montenegro shall:

   (a) ensure that the operator or manager of each establishment concerned takes all necessary measures to allow for the proper observance of in-house procedures for the separation of milk;

   (b) conduct tests and unannounced controls relating to the observance of milk separation; and

   (c) conduct tests in approved laboratories on all raw and finished products to verify their compliance with the requirements of Annex III, Section IX, Chapter II to Regulation (EC) No 853/2004, including the microbiological criteria for milk-based products.

5. Dairy products derived from non-compliant milk shall only:

   (a) be placed on the national market in Montenegro irrespective of the date of marketing; or

   (b) be placed on markets of third countries in accordance with relevant Union legislation.

6. Dairy products derived from non-compliant milk shall bear a different identification mark from that provided for in Article 5 of Regulation (EC) No 853/2004. A clear description of that mark shall be communicated to the Commission no later than one year before the date of accession.

7. Products based on compliant raw milk processed on a separate production line can be marketed as compliant products provided that all conditions regarding separation of product lines are maintained.

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8. Montenegro shall ensure gradual compliance of raw milk with applicable EU requirements and shall continuously monitor the implementation of the National Programme for the improvement of raw milk quality and shall provide the Commission with an annual report of progress made in bringing dairy holdings in compliance with Regulation (EC) No 853/2004.

The first annual report shall be submitted to the Commission by 31 December 2028, at the latest, and the second annual report by 31 December 2029, at the latest. The following form shall be used for those reports.

Region	Total number of dairy holdings 31.12.2028	Number of dairy holdings with non-compliant* milk 31.12.2028	% of non-compliant* holdings out of the total 31.12.2028	Total volume of non-compliant milk 31.12.2028	% of total volume of non-compliant milk 31.12.2028	Total number of dairy holdings 31.12.2029	Number of dairy holdings with non-compliant* milk 31.12.2029	% of non-compliant * holdings out of the total 31.12.2029	Total volume of non-compliant milk 31.12.2029	% of total volume of non-compliant milk 31.12.2029

* Compliance refers to compliance with the applicable maximum limits for total plate count and somatic cell count, determined using the rolling geometric mean over the relevant assessment periods specified in Annex III, Section IX, Chapter I, Part III, point 3(a)(i), to Regulation (EC) No 853/2004. Under this provision, compliance for raw cows' milk is assessed using a rolling geometric average over a two-month period (with at least two samples per month) for total plate count and a rolling geometric average over a three-month period (with at least one sample per month) for somatic cell count.

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9. Montenegro shall ensure that the delivery of non-compliant raw milk with such requirements terminates by 31 December 2030, at the latest.

10. The Commission may adopt detailed implementing rules to ensure the smooth operation of the above transitional regime in accordance with the procedure referred to in Article 58 of Regulation (EC) No 178/2002.

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