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EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/1760

of 26 May 2021

supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ⁽¹⁾, and in particular Article 37(4) thereof,

Whereas:

- (1) Regulation (EU) 2019/6 of the European Parliament and of the Council aims to enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection. In particular, it aims to contain the spread of antimicrobial resistance with concrete measures to promote a prudent and responsible use of antimicrobials in animals, in line with the 'One Health' approach ⁽²⁾.
- (2) Although the efficacy of all antimicrobials is important to preserve public health, some antimicrobials are deemed more crucial than others, based on being preferred options for the treatment of serious infections in humans and the availability or lack of alternative treatment options. When antimicrobial resistance develops to an antimicrobial agent used to treat a specific infection for which there are no treatment alternatives and that resistance spreads, the consequences to public health are significant and potentially life-threatening. Human health, animal health and the environment are interlinked and are all essential parts of the 'One Health' approach, thus antimicrobial management in one sector may affect antimicrobial resistance in the other sectors.
- (3) Article 37(4) of Regulation (EU) 2019/6 requires the Commission to adopt delegated acts establishing criteria that will allow the Commission to determine which antimicrobials or groups of antimicrobials should be reserved for human use.
- (4) Various international organisations and countries have developed criteria for specifying or ranking the importance of antimicrobials or antimicrobial classes for human and veterinary medicine. Those criteria were developed for use in risk management strategies related to antimicrobial use in human healthcare settings and animal use. Prioritising critically important antimicrobials for humans is a valuable tool to support an evidence-based approach to risk management.

⁽¹⁾ OJ L 4, 7.1.2019, p. 43.

⁽²⁾ Commission Communication of 29 June 2017 on a European One Health Action Plan against Antimicrobial Resistance (COM(2017) 339).

- (5) The criteria to determine which antimicrobials are to be reserved for human use should be clear and pertinent whilst reflecting the latest scientific evidence. Pursuant to Article 37(6), the Commission received advice from the European Medicines Agency ('the Agency') on 31 October 2019 ^(*). The Agency's advice has taken account of expert opinions from national competent authorities, the European Food Safety Authority and the European Centre for Disease Prevention and Control. In the context of the preparation of that advice, a scientific workshop involving members of the Agency's expert group and international organisations was organised in Brussels on 14 June 2019. The workshop allowed participants to exchange views and share expertise from a global perspective on the topic of how to establish such criteria. The outcome of those discussions was taken into consideration by the Agency's expert group in completing its advice and the Commission has taken into account that advice in accordance with Article 37(6) of Regulation (EU) 2019/6.
- (6) While a number of countries within and outside the Union have implemented measures to restrict the use of certain antimicrobials, few have specific legislation for banning their use in veterinary medicine. Banning the use of an antimicrobial in animals is one of the most severe risk management measures that can be taken, thus such measures should be taken cautiously. Whenever possible, other existing risk management measures should be favoured, such as improving animal husbandry, biosecurity and herd or flock management, making a better use of vaccination and restricting the use of antimicrobials to specific circumstances.
- (7) Antimicrobials to be used only for treatment of certain infections in humans should be designated on the basis of sound criteria. Those criteria should allow to identify those antimicrobials that are of high importance to preserve human health and that should therefore be considered for use in human medicine exclusively. The criteria should also enable to identify those antimicrobials, whose use in animals could accelerate the spread of antimicrobial resistance, or present a risk thereof, by allowing for the transmission of resistance, which may include cross-resistance or co-selection of resistance to other antimicrobials, from animals to humans. Finally, the criteria should allow to identify antimicrobials that do not represent an essential need for animal health, and whose absence of use in veterinary medicine would not lead to any significant negative impact on animal health.
- (8) While assessing whether an antimicrobial could be reserved for the treatment of certain infections in humans, it is important to determine whether its absence of use in veterinary medicine would result in significant morbidity or significant mortality or would have a major impact on animal welfare and public health. In the latter case, the availability of adequate alternative medicinal products for the treatment of the diseases concerned in the animals species concerned should be considered.
- (9) When considering the use of alternative medicinal products instead of certain antimicrobial medicinal products, it is important that those products are adequate and available. Such alternatives should be authorised medicinal products in suitable formulations for the treatment of the disease in the animal species requiring treatment. Their use should lead to a lower risk to public health in terms of antimicrobial resistance than the antimicrobial medicinal product it aims to replace.
- (10) In exceptional cases where there is scientific evidence showing an overriding public health interest, the criterion of non-essential need to animal health should envisage the possibility for an antimicrobial to be reserved for human use, even if no alternative medicinal product is available for veterinary medicine, provided that not using such an antimicrobial would only result in limited morbidity or limited mortality. In such exceptional cases, the fulfilment of the other two criteria (high importance to human health and risk of transmission of resistance) should be still required for such an antimicrobial to be reserved for human use.
- (11) Article 152(1) of Regulation (EU) 2019/6 indicates that existing products authorised in accordance with the previous legislation is to be deemed to be authorised in accordance with the Regulation, with the exception of authorisations of veterinary medicinal products containing antimicrobials that have been reserved for human use only. The criteria in the present act apply to antimicrobials that have not yet been authorised for the veterinary market but also apply to antimicrobials in existing veterinary medicinal products.

^(*) Advice on implementing measures under Article 37(4) of Regulation (EU) 2019/6 on veterinary medicinal products – Criteria for the designation of antimicrobials to be reserved for treatment of certain infections in humans (EMA/CVMP/158366/2019).

- (12) It is recognised that the necessary available evidence to assess the fulfilment of the criteria may vary depending on the marketing authorisation status of the antimicrobial or group of antimicrobials considered: (1) authorised in human medicine only; (2) authorised in veterinary medicine only; (3) authorised both in human and veterinary medicine; (4) authorised neither in human nor veterinary medicine. For that reason, the available evidence should be taken into account while applying the criteria.
- (13) This Regulation should apply from 28 January 2022 in accordance with Article 153(2) of Regulation (EU) 2019/6,

HAS ADOPTED THIS REGULATION:

Article 1

1. The criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans are set out in the Annex.
2. An antimicrobial or a group of antimicrobials shall meet all three criteria set out in Parts A, B and C in the Annex in order to be designated as reserved for treatment of certain infections in humans.

Article 2

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

It shall apply from 28 January 2022.

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

Done at Brussels, 26 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans

PART A

CRITERION OF HIGH IMPORTANCE TO HUMAN HEALTH

1. The antimicrobial or group of antimicrobials meets this criterion if any of the following applies:
 - (a) it is the sole or last-resort antimicrobial or group of antimicrobials available in a patient management treatment approach for serious, life-threatening infections in humans which, if inappropriately treated, would lead to significant debilitating morbidity or significant mortality;
 - (b) it is an essential component of the limited treatment alternatives available in a patient management treatment approach for serious, life-threatening infections in humans which, if inappropriately treated, would lead to significant debilitating morbidity or significant mortality;
 - (c) it is an antimicrobial or a group of antimicrobials, which is authorised in the Union for the treatment of serious microbial infections in patients with limited treatment options, indicating that the antimicrobial or the group of antimicrobials considered is recognised as addressing an unmet medical need related to antimicrobial resistance.
2. Factors considered responsible for limited treatment alternatives for patients, as referred to in point 1(b), include:
 - the virulence and antimicrobial resistant phenotype(s) of the microorganisms causing infection, including multidrug resistance,
 - the characteristics of the patients (for example, immunocompromised, paediatric, elderly) and disease (for example, site of infection concerned) under treatment,
 - the proportion of patients requiring treatment and the impact on healthcare services.

PART B

CRITERION OF RISK OF TRANSMISSION OF RESISTANCE

1. The antimicrobial or group of antimicrobials meets this criterion if any of the following applies:
 - (a) for an antimicrobial or group of antimicrobials authorised for use in animals, scientific evidence, including epidemiological evidence where available, exists showing that:
 - there is an actual emergence, dissemination and transmission of resistance to this antimicrobial or group of antimicrobials, or induction of cross-resistance or co-selection of resistance to other antimicrobials, and
 - transmission of such resistance from animal sources to humans is significant and linked to the use of this antimicrobial or group of antimicrobial in animals, whether it occurs through microorganisms resistant to the antimicrobial or group of antimicrobials considered or through the transmission of genes conferring resistance to the antimicrobial or group of antimicrobials considered;
 - (b) for an antimicrobial or group of antimicrobials not authorised for use in animals, scientific evidence exists showing that:
 - there is the potential for emergence, dissemination and transmission of resistance to this antimicrobial or group of antimicrobials or potential for inducing cross-resistance or co-selection of resistance to other antimicrobials, and

- this transmission from animal sources to humans would likely be significant and linked to the use of this antimicrobial or group of antimicrobials in animals, whether it would occur through microorganisms resistant to the antimicrobial or group of antimicrobials considered or through the transmission of genes conferring resistance to the antimicrobial or group of antimicrobials considered.
2. Factors triggering significant transmission of resistance between animals and humans linked to the use of an antimicrobial or group of antimicrobials in animals include:
- use selects for resistance, cross-resistance or co-selection of resistance to antimicrobials that are crucial for human medicine,
 - transmission of resistance occurs by vertical as well as horizontal transmission,
 - transmission of resistance involves zoonotic pathogens,
 - transmission can take place by different routes of exposure,
 - transmission occurs through a number of different animal species.

PART C

CRITERION OF NON-ESSENTIAL NEED FOR ANIMAL HEALTH

1. The antimicrobial or group of antimicrobials meets this criterion if any of the following applies:
- (a) there is no robust evidence of the need for the antimicrobial or group of antimicrobials in veterinary medicine;
 - (b) the antimicrobial or group of antimicrobials is used to treat serious, life-threatening infections in animals which, if inappropriately treated, would lead to significant morbidity or significant mortality, or would have a major impact on animal welfare or public health, but adequate alternative medicinal products are available for the treatment of those infections in the animal species concerned;
 - (c) the antimicrobial or group of antimicrobials is used to treat serious, life-threatening infections in animals which, if inappropriately treated, would lead to limited morbidity or limited mortality and there is scientific evidence showing an overriding public health interest in not using it.
2. The provisions laid down in point 1 apply when the antimicrobial or group of antimicrobials considered is either of the following:
- (a) an antimicrobial or group of antimicrobials present within authorised veterinary medicinal products;
 - (b) an antimicrobial or group of antimicrobials present within medicinal products authorised for use in humans, that may be administered to animals outside the terms of their marketing authorisation.
-

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1761**of 5 October 2021****extending a derogation from Council Regulation (EC) No 1967/2006 as regards the minimum distance from coast, the minimum sea depth and the prohibition to fish in protected habitats for shore seines fishing in territorial waters of Croatia**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1967/2006 of 21 December 2006 concerning management measures for the sustainable exploitation of fishery resources in the Mediterranean Sea amending Regulation (EEC) No 2847/93 and repealing Regulation (EC) No 1626/94 ⁽¹⁾ and in particular Article 4(5) and Article 13(5) and (10) thereof,

Whereas:

- (1) On 22 October 2018, the Commission adopted Implementing Regulation (EU) 2018/1586 ⁽²⁾ establishing a derogation from Article 4(1), first subparagraph and Article 13(1), first subparagraph of Regulation (EC) No 1967/2006 as regards the minimum distance from coast, the minimum sea depth and the prohibition to fish in protected habitats for shore seines fishing in territorial waters of Croatia. The derogation concerned the use of traditional shore seines 'girarica' and 'migavica' fishing for picarels (*Spicara smaris*), as well as for the use of traditional shore seine of large mesh size 'šabakun' fishing for greater amberjack (*Seriola dumerili*), traditional shore seine 'oližnica' fishing for sand smelt (*Atherina boyeri*) within the Croatian territorial waters. The derogation expires on 26 October 2021.
- (2) On 22 March 2021, the Commission received a request from Croatia for an extension of that derogation concerning the use of traditional shore seine 'oližnica', fishing for sand smelt (*Atherina boyeri*) and traditional shore seines 'girarica' and 'migavica', fishing for picarels (*Spicara smaris*) within the Croatian territorial waters. With the same request, Croatia requested the extension of the derogation of the first subparagraph of Article 4(1) of Regulation (EC) No 1967/2006, in relation to traditional shore seines 'girarica' and 'migavica', fishing for picarels (*Spicara smaris*).
- (3) Croatia provided up-to-date information and technical justifications for the renewal of that derogation.
- (4) Croatia adopted the management plan by Ministerial Ordinance ⁽³⁾ in accordance with Article 19(2) of Regulation (EC) No 1967/2006 ('Croatian management plan') on 15 September 2021.
- (5) The request concerns fishing activities already authorised by Croatia and covers vessels which have a track record of more than 5 years in the fishery and operate under the Croatian management plan.
- (6) The request covers 71 vessels listed in the Croatian management plan regulating operations of shore seines in Croatian territorial waters, and the Croatian management plan guarantees no further increase of the fishing effort, as required by Article 13(9) of Regulation (EC) No 1967/2006.
- (7) Those vessels are included on a list communicated to the Commission in line with Article 13(9) of Regulation (EC) No 1967/2006.

⁽¹⁾ OJ L 409, 30.12.2006, p. 11.

⁽²⁾ Commission Implementing Regulation (EU) 2018/1586 of 22 October 2018 establishing a derogation from Council Regulation (EC) No 1967/2006 as regards the minimum distance from coast, the minimum sea depth and the prohibition to fish above protected habitats for shore seines fishing in territorial waters of Croatia (OJ L 264, 23.10.2018, p. 16).

⁽³⁾ 'Pravilnik o obavljanju gospodarskog ribolova na moru obalnim mrežama potegačama, OJ 30/18 and its amendments 49/18, 78/18, 54/19, 27/21 and 100/21'

- (8) The Scientific, Technical and Economic Committee for Fisheries (‘STECF’) assessed the extension of the derogation requested by Croatia and the related Croatian management plan at its plenary session from 22 to 26 March 2021 ⁽⁴⁾.
- (9) STECF noted that the management plan presents major improvements compared with the previous one, regarding in particular selectivity improvements, and attempts to conduct exploratory stock assessments and reference points.
- (10) The extension of the derogation requested by Croatia comply with the conditions set out in Article 4(5) and Article 13(5) and (9) of Regulation (EC) No 1967/2006.
- (11) The extension of the derogation requested by Croatia affects a limited number of vessels, compared with the large distribution area of the total national fleets, representing less than 1 % of the entire Croatian fleet and less than 1 % of the gross tonnage (‘GT’) of all national fleet.
- (12) There are specific geographical constraints which limit the fishing grounds given both the distinct morphological structure of Croatia, comprising of long coastline including numerous islands and the spatial distribution of the target species, which is exclusively limited in certain specific sites and zones in the coastal areas at depths of less than 50 meters.
- (13) With respect to fishing for picarels by shore seines ‘girarica’ and ‘migavica’, the request concerns fishing activities by vessels of less than or equal to 12 meters overall length and engine power of less than or equal to 85 kW with bottom towed nets traditionally undertaken on *Posidonia* beds, in accordance with Article 4(5), first subparagraph of Regulation (EC) No 1967/2006. In addition, the fishing activity with respect to picarels fishing affects approximately 4 % of the area covered by seagrass beds of *Posidonia oceanica*, within the area covered by the management plan, and less than 3 % of seagrass beds, in the territorial waters of Croatia, in accordance with the requirements of Article 4(5), first subparagraph, points (ii) and (iii) of Regulation (EC) No 1967/2006.
- (14) The fishery cannot be undertaken with other gears, since only shore seines have the technical characteristic necessary to carry out this type of fishery.
- (15) Moreover, the fishery has no significant impact on the marine environment, as shore seines are very selective gears. The Croatian management plan sets out all relevant definitions on the fisheries concerned and guarantees that fishing authorisations will be issued only to specified 71 vessels that are authorised to fish by Croatia. In this respect, it is noted that, in line with the Croatian management plan and the Ministerial Ordinance, the fishing grounds for shore seines nets ‘miavica’, ‘girarica’ and ‘oližnica’ are established in Annex II of the Croatian management plan, while shore seines ‘oližnica’ fishing for sand smelt, shall be permitted only in the defined area of fishing subzone ‘E4’ and part of the subzone ‘F2’. Additionally, the use of shore seine nets is prohibited in the areas identified as national parks and special habitats.
- (16) The fishing activities concerned fulfil the requirements of Article 4(1), second paragraph of Regulation (EC) No 1967/2006, as the seines are hauled in the water column and do not touch the seabed.
- (17) The requirements of Article 8(1), point (h) of Regulation (EC) No 1967/2006, as replaced by Article 8(1) and Annex IX, Part B, section I to Regulation (EU) 2019/1241 of the European Parliament and of the Council ⁽⁵⁾, are not applicable since they relate to trawlers.

⁽⁴⁾ Scientific, Technical and Economic Committee for Fisheries (STECF) – 66th Plenary Report (PLEN-21-01). EUR 28359 EN, Publications Office of the European Union, Luxembourg, 2021, available here: https://stecf.jrc.ec.europa.eu/reports/plenary/-/asset_publisher/os6k/document/id/2851300

⁽⁵⁾ Regulation (EU) 2019/1241 of the European Parliament and of the Council of 20 June 2019 on the conservation of fisheries resources and the protection of marine ecosystems through technical measures, amending Council Regulations (EC) No 1967/2006, (EC) No 1224/2009 and Regulations (EU) No 1380/2013, (EU) No 2016/1139, (EU) 2018/973, (EU) 2019/472 and (EU) 2019/1022 of the European Parliament and of the Council, and repealing Council Regulations (EC) No 894/97, (EC) No 850/98, (EC) No 2549/2000, (EC) No 254/2002, (EC) No 812/2004 and (EC) No 2187/2005 (OJ L 198, 25.7.2019, p. 105).

- (18) Croatia authorised a derogation from the minimum mesh size with regard to use of traditional shore seines 'oližnica' fishing for sand smelt (*Atherina boyeri*) established in Article 9(3) of Regulation (EC) No 1967/2006 on the basis of the fulfillment of the requirements of Article 9(7) of that Regulation given the highly selective nature of the fisheries concerned, its negligible effect on the marine environment and that it is not affected by the provisions in Article 4(5) of Regulation (EC) No 1967/2006.
- (19) Article 9 of Regulation (EC) No 1967/2006 was deleted by Regulation (EU) 2019/1241. However, according to Annex IX, Part B, point 4 to Regulation (EU) 2019/1241, derogations from minimum mesh sizes adopted on basis of Article 9 of Regulation (EC) No 1967/2006, that were in force on 14 August 2019, can continue to apply, provided they do not lead to the increase in catches of juveniles. The extension of the derogation requested by Croatia complies with the conditions laid down in Article 15(5) of Regulation (EC) No 1967/2006 and in Annex IX, Part B, point 4 to Regulation (EU) 2019/1241, as it does not lead to a deterioration of selectivity standards, in particular in terms of an increase in the catches of juveniles, existing on 14 August 2019, and aims at achieving the objectives and targets set out in Articles 3 and 4 of that Regulation.
- (20) The Commission notes that Croatia did not authorise a derogation in its management plan from the requirements of Article 9(3) of Regulation (EC) No 1967/2006, as replaced by Article 8(1) and Annex IX, Part B, point 4 of Regulation (EU) 2019/1241, with regard to use of traditional shore seines 'girarica' and 'migavica', fishing for picarels (*Spicara smaris*).
- (21) The fishing activities concerned take place at 500 meters from the coast and therefore do not interfere with the activities of other vessels.
- (22) The Croatian management plan ensures that catches of species mentioned in Annex IX, Part A to Regulation (EU) 2019/1241 are minimal, since the targeted species are sand smelt (*Atherina boyeri*) and picarels (*Spicara smaris*), which are not mentioned in Annex IX, Part A to Regulation (EU) 2019/1241.
- (23) Fishing activities are highly selective and do not target cephalopods.
- (24) The Croatian management plan includes measures for the monitoring of fishing activities, as provided for in Article 4(5), fifth subparagraph and Article 13(9), third subparagraph of Regulation (EC) No 1967/2006.
- (25) The fishing activities concerned fulfill the requirements set out in Article 14 of Council Regulation (EC) No 1224/2009 ⁽⁶⁾.
- (26) The requested derogations should therefore be extended for two years.
- (27) Croatia should report to the Commission in due time and in accordance with the monitoring plan provided for in the Croatian management plan.
- (28) A limitation in duration of the derogation will allow ensuring prompt corrective management measures in case the report to the Commission shows a poor conservation status of the exploited stocks, while providing scope to enhance the scientific basis for an improved management plan.
- (29) Since the derogation granted by Implementing Regulation (EU) 2018/1586 expired on 26 October 2021, in order to ensure legal continuity, this Regulation should apply with effect from 27 October 2021.

⁽⁶⁾ Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006 (OJ L 343, 22.12.2009, p. 1).

- (30) For reasons of legal certainty, this Regulation should enter into force as a matter of urgency.
- (31) This Regulation is without prejudice to the Commission's position regarding compliance of the activity covered by this derogation with other EU legislation, in particular Council Directive 92/43/EEC ⁽⁷⁾.
- (32) The measures provided for in the Regulation are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS REGULATION:

Article 1

Derogation

1. Article 4(1), first subparagraph of Regulation (EC) No 1967/2006 shall not apply in the territorial waters of Croatia to vessels fishing for picarels (*Spicara smaris*) by shore seines 'girarica' and 'migavica'.
2. Article 13(1), first subparagraph of Regulation (EC) No 1967/2006 shall not apply in the territorial waters of Croatia to vessels active in the following fisheries:
 - (a) sand smelt (*Atherina boyeri*) by shore seines 'oližnica'; and
 - (b) picarels (*Spicara smaris*) by shore seines 'girarica' and 'migavica';
3. The shore seines referred to in paragraphs 1 and 2 shall be used by vessels:
 - (a) bear a registration number set out in the Croatian management plan adopted by Croatia
 - (b) have a track record in the fishery for more than 5 years and not involving any further increase in the fishing effort deployed; and
 - (c) hold a fishing authorisation and operate under the Croatian management plan in accordance with Article 19(2) of Regulation (EC) No 1967/2006.

Article 2

Monitoring plan and report

Croatia shall communicate to the Commission, by 26 October 2023, a report drawn up in accordance with the monitoring plan established in the Croatian management plan referred to in Article 1(3), point (c).

Article 3

Entry into force

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

It shall apply from 27 October 2021 to 26 October 2023.

⁽⁷⁾ Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7).

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 5 October 2021.

For the Commission
The President
Ursula VON DER LEYEN

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