

Official Journal of the European Union

L 135



English edition

Legislation

Volume 65

12 May 2022

Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Regulation (EU) 2022/727 of 11 May 2022 refusing to authorise a health claim made on foods and referring to the reduction of disease risk ⁽¹⁾..... 1**

DECISIONS

- ★ **Commission Implementing Decision (EU) 2022/728 of 13 April 2022 on the inconsistency of certain performance targets contained in the draft national and functional airspace block performance plans submitted by Belgium, Germany, Greece, France, Cyprus, Latvia, Luxembourg, Malta, the Netherlands, Romania, and Sweden pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council with the Union-wide performance targets for the third reference period and setting out recommendations for the revision of those targets (notified under document C(2022) 2283) ⁽¹⁾..... 4**
- ★ **Commission Implementing Decision (EU) 2022/729 of 11 May 2022 amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for quality management systems and for application of risk management to medical devices 31**

⁽¹⁾ Text with EEA relevance.

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.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2022/727

of 11 May 2022

refusing to authorise a health claim made on foods and referring to the reduction of disease risk**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ⁽¹⁾, and in particular Article 17(3) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006, health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and are included in the list of permitted claims.
- (2) With regard to health claims on reduction of disease risk, Article 15 of Regulation (EC) No 1924/2006 provides that applications for authorisations of health claims shall be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'.
- (3) Following receipt of an application, the Authority is to inform without delay the other Member States and the Commission thereof, and to deliver an opinion on the health claim concerned.
- (4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.
- (5) Following an application from Han-Biotech GmbH submitted via the competent authority of Germany pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to Symbiosal® and the lowering of blood pressure and a reduced risk of hypertension (Question No EFSA-Q-2018-00002). The claim proposed by the applicant was worded as follows: "Symbiosal®" has been shown to lower the rising of blood pressure when used as a replacement of traditional table salt. The rising of blood pressure is a risk factor for high blood pressure (hypertension)'.
- (6) On 25 July 2018, the Commission and the Member States received the scientific opinion from the Authority ⁽²⁾, which concluded that on the basis of the data presented a cause and effect relationship has not been established between the consumption of 'Symbiosal®' and lowering of blood pressure. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.⁽²⁾ EFSA Journal 2018;16(7):5364.

- (7) The comments from the applicant received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting out the measure provided for in this Regulation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The health claim listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

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*.

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

Done at Brussels, 11 May 2022.

For the Commission
The President
Ursula VON DER LEYEN

Rejected health claim

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk.	'Symbiosal®' (a food supplement containing sea salt (97 %) plus chitosan (3 %)).	'Symbiosal®' has been shown to lower the rising of blood pressure when used as a replacement of traditional table salt. The rising of blood pressure is a risk factor for high blood pressure (hypertension).	Q-2018-00002

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2022/728

of 13 April 2022

on the inconsistency of certain performance targets contained in the draft national and functional airspace block performance plans submitted by Belgium, Germany, Greece, France, Cyprus, Latvia, Luxembourg, Malta, the Netherlands, Romania, and Sweden pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council with the Union-wide performance targets for the third reference period and setting out recommendations for the revision of those targets

(notified under document C(2022) 2283)

(Only the Dutch, English, French, German, Greek, Latvian, Maltese, Romanian and Swedish texts are authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation) ⁽¹⁾, and in particular Article 11(3), point (c), second subparagraph thereof,

After consulting the Single Sky Committee,

Whereas:

GENERAL CONSIDERATIONS

Background

- (1) Pursuant to Article 11 of Regulation (EC) No 549/2004 a performance scheme for air navigation services and network functions is to be set up. Furthermore, pursuant to Article 10 of Commission Implementing Regulation (EU) 2019/317 ⁽²⁾ Member States are to draw up, either at national level or at the level of functional airspace blocks ('FABs'), binding performance targets for each reference period of the performance scheme for air navigation services and network functions. Those performance targets have to be consistent with the Union-wide targets adopted by the Commission for the reference period concerned. The Commission is responsible for assessing whether the proposed performance targets contained in the draft performance plans are consistent with the Union-wide performance targets, on the basis of the assessment criteria set out in Annex IV to Implementing Regulation (EU) 2019/317.
- (2) The outbreak of the COVID-19 pandemic has, since the first quarter of calendar year 2020, significantly impacted the air transport sector and has considerably reduced air traffic volumes as compared to pre-pandemic levels, due to the measures taken by the Member States and third countries to contain the pandemic.

⁽¹⁾ OJ L 96, 31.3.2004, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2019/317 of 11 February 2019 laying down a performance and charging scheme in the single European sky and repealing Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013 (OJ L 56, 25.2.2019, p. 1).

- (3) Union-wide performance targets for the third reference period ('RP3') were initially set out in Commission Implementing Decision (EU) 2019/903 ⁽³⁾. As those Union-wide performance targets and the draft RP3 performance plans subsequently submitted by the Member States were drawn up before the outbreak of the COVID-19 pandemic, they could not take account of the resulting significantly changed circumstances for air transport.
- (4) In response to the impact of the COVID-19 pandemic on the provision of air navigation services, exceptional measures for RP3, which derogate from the provisions of Implementing Regulation (EU) 2019/317, were set out in Commission Implementing Regulation (EU) 2020/1627 ⁽⁴⁾. Pursuant to Article 2(1) of Implementing Regulation (EU) 2020/1627, the Commission adopted, on 2 June 2021, Commission Implementing Decision (EU) 2021/891 ⁽⁵⁾ setting revised Union-wide performance targets for RP3 in the key performance areas of safety, environment, capacity and cost-efficiency.
- (5) All Member States have developed and adopted draft performance plans containing revised local performance targets for RP3, which were submitted to the Commission for assessment by 1 October 2021. Following the verification of completeness of those draft performance plans, the Commission requested Member States to submit updated draft performance plans by 17 November 2021. The Commission's assessment included in this Decision is based on the updated draft performance plans submitted by Member States.
- (6) The performance review body, assisting the Commission in the implementation of the performance scheme pursuant to Article 11(2) of Regulation (EC) No 549/2004, has submitted to the Commission a report containing its advice on the assessment of RP3 draft performance plans.

Criteria for the assessment

- (7) In accordance with Article 14(1) of Implementing Regulation (EU) 2019/317, the Commission has assessed the consistency of national targets or targets at the level of FABs on the basis of the assessment criteria laid down in point 1 of Annex IV to that Implementing Regulation, and taking account of local circumstances. In respect of each key performance area and the related performance targets, the Commission has complemented the assessment by reviewing draft performance plans in respect of the elements set out in point 2 of Annex IV to that Implementing Regulation.
- (8) Concerning the key performance area of safety, the Commission has assessed the consistency of the targets submitted by Member States regarding the effectiveness of safety management of air navigation service providers based on the criterion laid down in point 1.1 of Annex IV to Implementing Regulation (EU) 2019/317. That assessment was conducted taking account of local circumstances and was complemented by the review of measures planned for achievement of the safety targets in respect of the elements set out in point 2.1.(a) of Annex IV to Implementing Regulation (EU) 2019/317. The Commission has found that the local safety performance targets proposed by all Member States are consistent with the corresponding Union-wide performance targets and therefore no related findings are set out in this Decision.
- (9) Concerning the key performance area of environment, the consistency of the targets submitted by Member States regarding the average horizontal *en route* flight efficiency of the actual trajectory has been assessed on the basis of the criterion laid down in point 1.2 of Annex IV to Implementing Regulation (EU) 2019/317. Accordingly, the proposed targets contained in the draft performance plan have been compared to the relevant *en route* horizontal flight efficiency reference values set out in the European Route Network Improvement Plan. That assessment was conducted taking account of local circumstances and was complemented by the review of measures planned for achievement of the environment targets in respect of the elements set out in point 2.1.(a) of Annex IV to Implementing Regulation (EU) 2019/317.

⁽³⁾ Commission Implementing Decision (EU) 2019/903 of 29 May 2019 setting the Union-wide performance targets for the air traffic management network for the third reference period starting on 1 January 2020 and ending on 31 December 2024 (OJ L 144, 3.6.2019, p. 49).

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/1627 of 3 November 2020 on exceptional measures for the third reference period (2020-2024) of the single European sky performance and charging scheme due to COVID-19 pandemic (OJ L 366, 4.11.2020, p. 7).

⁽⁵⁾ Commission Implementing Decision (EU) 2021/891 of 2 June 2021 setting revised Union-wide performance targets for the air traffic management network for the third reference period (2020-2024) and repealing Implementing Decision (EU) 2019/903 (OJ L 195, 3.6.2021, p. 3).

- (10) In respect of the calendar year 2020, the Union-wide performance target for RP3 in the key performance area of environment, which was initially set out in Implementing Decision (EU) 2019/903, was not revised by Implementing Decision (EU) 2021/891, considering that the time period for the application of that target had expired and that its implementation had thus become definitive, leaving no possibility for retroactive adjustment. Accordingly, it was not appropriate for Member States to revise, in the draft performance plans submitted by 1 October 2021, their local performance targets for calendar year 2020 in the key performance area of environment. In light of those considerations, the consistency of the local environment performance targets with the corresponding Union-wide performance targets was assessed with regard to calendar years 2021, 2022, 2023 and 2024. On that basis, the Commission has found that the local environment performance targets proposed by all Member States are consistent with the corresponding Union-wide performance targets and therefore no related findings are set out in this Decision.
- (11) Concerning the key performance area of capacity, the consistency of the targets submitted by Member States regarding the average *en route* air traffic flow management ('ATFM') delay per flight has been assessed on the basis of the criterion laid down in point 1.3 of Annex IV to Implementing Regulation (EU) 2019/317. Accordingly, the proposed targets contained in the draft performance plan have been compared to the relevant reference values set out in the Network Operations Plan. That assessment was conducted taking account of local circumstances and was complemented by the review of measures planned for achievement of the *en route* capacity targets, including in particular the review of planned major investments and the review of the incentive scheme or schemes in respect of the elements set out in point 2.1.(a) of Annex IV to Implementing Regulation (EU) 2019/317.
- (12) In respect of the calendar year 2020, the Union-wide performance target for RP3 in the key performance area of capacity, which was initially set out in Implementing Decision (EU) 2019/903, was not revised by Implementing Decision (EU) 2021/891, considering that the time period for the application of that target had expired and that its implementation had thus become definitive, leaving no possibility for retroactive adjustment. Accordingly, it was not appropriate for Member States to revise, in the draft performance plans submitted by 1 October 2021, their local performance targets for calendar year 2020 in the key performance area of capacity. In light of those considerations, the consistency of the local capacity performance targets with the corresponding Union-wide performance targets was assessed with regard to calendar years 2021, 2022, 2023 and 2024.
- (13) Furthermore, in relation to the assessment of draft *en route* capacity targets, for airports which are in the scope of Implementing Regulation (EU) 2019/317 in accordance with Articles 1(3) and (4) of that Regulation, the Commission has complemented its assessment by the review of the draft capacity targets for terminal air navigation services in accordance with point 2.1(b) of Annex IV to Implementing Regulation (EU) 2019/317. Where those draft targets were found to raise concerns, the related findings are set out in this Decision.
- (14) Concerning the key performance area of cost-efficiency, the consistency of the targets submitted by Member States regarding determined unit costs ('DUC') for *en route* air navigation services has been assessed based on the criteria laid down in points 1.4(a), 1.4(b) and 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317. Those criteria consist of the determined unit cost trend over RP3, the long-term determined unit cost trend over the second reference period ('RP2') and RP3 (2015-2024), and the baseline value for the determined unit cost at charging zone level compared with the average value of the charging zones where air navigation service providers have a similar operational and economic environment.
- (15) Where the *en route* cost-efficiency targets were found to be inconsistent with the criteria laid down in points 1.4(a), 1.4(b) and 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission has further examined, in light of the justifications and evidence provided in the performance plans concerned, whether a deviation could be deemed necessary and proportionate on the basis of point 1.4(d) of Annex IV to Implementing Regulation (EU) 2019/317, provided that the deviation from the Union-wide determined unit cost trend or from the long-term Union-wide determined unit cost trend is exclusively due to additional determined costs related to measures necessary to achieve the performance targets in the key performance area of capacity or to restructuring measures within the meaning of Article 2(18) of Implementing Regulation (EU) 2019/317.

- (16) The assessment of *en route* cost efficiency targets was conducted taking account of local circumstances. It was complemented by the review of the elements laid down in point 2 of Annex IV to Implementing Regulation (EU) 2019/317, namely the key factors and parameters underpinning those targets as set out under point 2.1(d) of that Annex.
- (17) Furthermore, in relation to the assessment of draft *en route* cost-efficiency targets, for airports which are in the scope of Implementing Regulation (EU) 2019/317 in accordance with Articles 1(3) and (4) of that Regulation, the Commission has complemented its review with the assessment of the draft cost-efficiency targets for terminal air navigation services in accordance with point 2.1(c) of Annex IV to Implementing Regulation (EU) 2019/317. Where those draft targets were found to raise concerns, the related findings are set out in this Decision.
- (18) In accordance with point 2(f) of Annex IV to Implementing Regulation (EU) 2019/317, in relation to the assessment of draft capacity targets, the Commission has complemented its review by an assessment of the draft incentive schemes referred to in Article 11 of Implementing Regulation (EU) 2019/317. In this respect, the Commission has examined whether the draft incentive schemes fulfil the substantive requirements set out in Article 11(1) and (3) of Implementing Regulation (EU) 2019/317. Where those draft incentive schemes were found to raise concerns, the related findings are set out in this Decision.

Special considerations concerning traffic evolution

- (19) The STATFOR October 2021 base traffic forecast projects that air traffic at Union-wide level will reach its pre-pandemic levels in the course of 2023 and will exceed those levels in 2024. However, the level of uncertainty regarding traffic development remains particularly high, because of the risks related to the evolution of the COVID-19 epidemiological situation. The Commission notes that the traffic recovery is expected to be uneven across Member States.
- (20) Accordingly, the forecasted RP3 traffic growth in several Member States is foreseen to be significantly lower than the average traffic growth at Union-wide level, and RP3 traffic volumes are forecasted to remain below pre-pandemic levels in a number of those Member States. The Commission acknowledges that this renders the achievement of Union-wide cost-efficiency targets more demanding for the Member States concerned, and has taken this point into account when reviewing the local circumstances relevant for the assessment of each draft performance plan.

FINDINGS CONCERNING FABEC

Assessment of draft performance targets in the key performance area of cost-efficiency – Belgium and Luxembourg

- (21) The draft *en route* cost-efficiency targets proposed by Belgium and Luxembourg for RP3 are as follows:

<i>En route</i> charging zone of Belgium and Luxembourg	2014 baseline value	2019 baseline value	2020 -2021	2022	2023	2024
Draft <i>en route</i> cost-efficiency targets, expressed as determined <i>en route</i> unit cost (in real terms at 2017 prices)	73,13 EUR	83,28 EUR	189,52 EUR	113,26 EUR	108,51 EUR	103,82 EUR

- (22) As regards the criterion laid down in point 1.4(a) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the *en route* determined unit cost trend of Belgium and Luxembourg at charging zone level of +5,7 % per year over RP3 underperforms the Union-wide trend of +1,0 % over the same period.

- (23) As regards the criterion laid down in point 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the long-term *en route* determined unit cost trend of Belgium and Luxembourg at charging zone level over RP2 and RP3 of +4,0 % per year underperforms the long-term Union-wide trend of -1,3 % over the same period.
- (24) As regards the criterion laid down in point 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the baseline value for the determined unit cost of EUR 83,28 of Belgium and Luxembourg, expressed in real terms at 2017 prices ('EUR2017'), is 13,2 % higher than the average baseline value of EUR 73,56 in EUR2017 of the relevant comparator group. The Commission notes that that difference becomes even larger during RP3, as the determined *en route* unit cost of Belgium and Luxembourg for 2024 is higher by 49,9 % than the average of the comparator group.
- (25) Furthermore, it is necessary to examine whether the deviations observed above from the criteria set out in points 1.4(a), 1.4(b) and 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317 may be deemed necessary and proportionate under point 1.4(d) of that Annex.
- (26) The Commission notes that the difference estimated by the performance review body between the RP3 determined *en route* costs reported in the draft performance plan and the determined costs that would be required to meet the RP3 Union-wide determined unit cost trend is approximately EUR 41 M in EUR2017, whilst a corresponding estimated deviation from the long-term Union-wide trend amounts to approximately EUR 92,6 M in EUR 2017.
- (27) In respect of the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission notes that Belgium and Luxembourg refer in the draft performance plan to the additional determined costs incurred over RP3 by the *en route* air navigation service providers skeyes and MUAC in relation to measures to increase capacity.
- (28) On the one hand, it is highlighted in the draft performance plan that the complexity of the Belgium-Luxembourg airspace constitutes a factor increasing the relative workload of air traffic controllers and thus weighting negatively on air traffic controller productivity and on the *en route* cost base. This is explained by Belgium and Luxembourg to be one of the key drivers behind the deviation from the Union-wide determined unit cost trend.
- (29) On the other hand, Belgium and Luxembourg contend that both of the *en route* air navigation service providers ('ANSPs'), namely skeyes and MUAC, are facing specific challenges in relation to the provision of adequate capacity to accommodate the air traffic demand during RP3 and beyond.
- (30) Regarding skeyes, it is firstly outlined in the draft performance plan that a high number of retirements of air traffic controllers is expected during RP3 and the fourth reference period ('RP4'), on the grounds of the current age structure of the air traffic controller workforce.
- (31) It is reported that the applicable Belgian legislation prescribes that air traffic controllers must be withdrawn from duty five years before their retirement date. During those five years, they are eligible for pre-retirement (referred to as the 'DISPO' scheme) and receive an allowance equalling between 75 % and 85 % of their last salary. According to the information provided in the draft performance plan, air traffic controllers are currently placed in DISPO at the age of 56 and this age limit is due to be lifted to 57. From 2025 onwards, 30 % of the operational air traffic controllers of skeyes are reaching the pre-retirement age during RP3, whilst an additional 20 % of operational air traffic controllers are foreseen to access pre-retirement in RP4.
- (32) skeyes plans to recruit and train new air traffic controllers in order to replace the planned retirements and deliver capacity commensurate with the forecasted traffic demand. According to the draft performance plan, skeyes will incur in this respect additional costs allocated to the *en route* cost base over the whole reference period, including the costs related to the DISPO pre-retirement scheme.

- (33) Furthermore, it is pointed out in the draft performance plan that skeyes intends to replace its air traffic management ('ATM') system with a single, integrated and harmonized airspace management system with MUAC and the Belgian Defense, which is considered essential in order to support the integration of civil and military ATM services and to enhance capacity and operational efficiencies.
- (34) With regard to MUAC, Belgium and Luxembourg refer to the collective agreement concluded in 2019 which, in essence, aims to increase the availability of air traffic controllers in order to mitigate the gap between staff availability and traffic demand. The flexibility provisions introduced into the agreement are accompanied by an increase of salary scales by nearly 11 %, which impacts the cost base over the whole reference period.
- (35) MUAC is also reported to incur additional costs over RP3 in relation to specific enhancements of its post-operations analysis process and of related tools, which aims to further optimise the planning of daily operations.
- (36) The Commission found that the deviations referred to in recital 26 cannot be exclusively attributed to the additional costs associated with capacity-related measures, including the costs related to the recruitment and training of new air traffic controllers and the costs of capacity-related major investments. Consequently, the Commission concluded that the reported cost deviations from the Union-wide determined unit cost trends in respect of Belgium and Luxembourg are too significant to be exclusively attributed to the reported measures for achieving local capacity targets.
- (37) Therefore, the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317 is not fulfilled in respect of Belgium and Luxembourg.
- (38) In respect of the criterion set out in point 1.4(d)(ii) of Annex IV to Implementing Regulation (EU) 2019/317, it suffices to mention that Belgium and Luxembourg have not presented in the draft performance plan any restructuring measures which would justify a deviation from the Union-wide determined unit cost trend or from the Union-wide long-term determined unit cost trend. Therefore, the criterion set out in point 1.4(d)(ii) is not fulfilled in respect of Belgium and Luxembourg.
- (39) In relation to the elements for review set out in point 2.1.(d)(vii) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that a revised cost allocation methodology has been established for the purpose of apportioning of the determined costs between *en route* and terminal services for RP3 in respect of Belgium. The proposed changes concern the allocation of the costs of approach control services incurred by skeyes and the allocation of the costs related to NSA costs. The Commission notes that the proposed changes lead in particular to the cost of approach control services to be entirely allocated to the *en route* charging zone.
- (40) The Commission has doubts as to the compliance of the change in the cost allocation methodology referred to in recital 93 with the requirements laid down in Article 15(2), point (e), of Regulation (EC) No 550/2004 and Article 22(5) of Implementing Regulation (EU) 2019/317. The Commission will further examine the related elements at the stage of assessing the revised draft performance plan of FABEC in respect of the air navigation service provider concerned.
- (41) On the grounds of the findings set out in recitals 21 to 40, the proposed targets included in the draft performance plan of FABEC, as regards the *en route* charging zone of Belgium and Luxembourg, should be assessed as inconsistent with the Union-wide performance targets in the key performance area of cost-efficiency.

Review of draft cost-efficiency targets for terminal air navigation services – Belgium

- (42) The Commission has concerns as regards the draft terminal cost-efficiency performance targets of Belgium in accordance with point 2.1(c) of Annex IV to Implementing Regulation (EU) 2019/317.

- (43) Firstly, when comparing the RP3 terminal determined unit cost trend with the *en route* determined unit cost trend, the Commission has found that the terminal determined unit cost trend of Belgium's terminal charging zone of +6,3 % is higher than Belgium's *en route* determined unit cost trend at charging zone level of +5,7 % over RP3.
- (44) Secondly, the Commission observes that the draft targets for the terminal determined unit cost trend for Belgium's terminal charging zone of +6,3 % over RP3 is higher than the actual terminal determined unit cost trend of +0,5 % observed over RP2.
- (45) Thirdly, when comparing the draft national targets of the terminal determined unit cost trend with the performance of similar airports for RP3, the Commission observes that the determined unit cost for Brussels Airport is estimated to be above the median determined unit cost of the relevant comparator group by a significant margin.
- (46) Therefore, the Commission considers that Belgium should further justify the terminal cost-efficiency targets in light of the observations above, or should revise downwards the draft targets for the terminal determined unit cost for RP3.

Review of the incentive schemes referred to in Article 11 of Implementing Regulation (EU) 2019/317 complementing the Commission's assessment of draft capacity targets – FABEC

- (47) With regard to the elements for review set out in point 2.1(f) of Annex IV to the Implementing Regulation (EU) 2019/317, the Commission observes that the draft *en route* capacity incentive scheme proposed in FABEC's draft performance plan comprises a maximum financial advantage equal to the maximum financial disadvantage, both of which amount to 0,5 % of determined costs.
- (48) On the basis of expert advice provided by the performance review body, the Commission has strong doubts whether the proposed maximum financial disadvantage, which amounts to 0,5 % of determined costs, would have any material impact on the revenue at risk, as required pursuant to point (a) of Article 11(3) of Implementing Regulation (EU) 2019/317.
- (49) As regards the terminal capacity incentive schemes proposed for the terminal charging zones of Belgium, France and the Netherlands, the Commission has doubts whether the proposed maximum financial disadvantages, which amount in respect of all of those incentive schemes to 0,5 % of determined costs, would have a material impact on the revenue at risk, as required pursuant to point (a) of Article 11(3) of Implementing Regulation (EU) 2019/317.
- (50) As regards the terminal capacity incentive scheme proposed for the terminal charging zone of Luxembourg, the Commission has doubts whether the proposed maximum financial disadvantage, which amounts to 0,25 % of determined costs, would have a material impact on the revenue at risk, as required pursuant to point (a) of Article 11(3) of Implementing Regulation (EU) 2019/317.
- (51) Therefore, Belgium, France, Germany, Luxembourg and the Netherlands, in respect of the draft performance plan submitted by FABEC, should revise their draft incentive schemes for achieving *en route* capacity targets so that the maximum financial disadvantages stemming from those incentive schemes are set at a level having a material impact on the revenue at risk, as expressly required under Article 11(3), point (a), of Implementing Regulation (EU) 2019/317, which in the Commission's view should lead to a maximum financial disadvantage equal to or higher than 1 % of determined costs.
- (52) In addition, Belgium, France, Luxembourg and the Netherlands, in respect of the draft performance plan submitted by FABEC, should revise their draft incentive schemes for achieving terminal capacity targets so that the maximum financial disadvantages stemming from those incentive schemes are set at a level having a material impact on the revenue at risk, as expressly required under Article 11(3), point (a), of Implementing Regulation (EU) 2019/317, which in the Commission's view should lead to a maximum financial disadvantage equal to or higher than 1 % of determined costs.

FINDINGS CONCERNING GREECE

Assessment of draft performance targets in the key performance area of capacity

- (53) The draft capacity targets proposed by Greece, expressed in minutes of *en route* ATFM delay per flight, and the corresponding national reference values for RP3 set out in the Network Operations Plan of September 2021 are as follows:

	2021	2022	2023	2024
Draft <i>en route</i> capacity targets of Greece, in minutes of ATFM delay per flight	0,32	0,26	0,20	0,20
Reference values for Greece, in minutes of ATFM delay per flight	0,10	0,14	0,15	0,15

- (54) The Commission observes that the draft capacity targets proposed by Greece for calendar years 2021 to 2024 are higher than the corresponding national reference values set out in the Network Operations Plan of September 2021. In this respect, the greatest deviation of draft capacity targets from the corresponding national reference values is observed for calendar year 2021.
- (55) The Commission notes that the capacity enhancement measures outlined in the draft performance plan comprise only part of the measures which had been set out in the Network Operations Plan of September 2021. Those measures include major investments into the upgrade of ATM infrastructure, recruitment of a total of 70 full-time equivalents as area control centre air traffic controllers during calendar year 2022 as well as airspace restructuring measures.
- (56) However, the Commission observes that several relevant capacity enhancement measures which are contained in the Network Operations Plan of September 2021 are not included in the draft performance plan submitted by Greece, which may result in a capacity gap during calendar years 2023 and 2024. Based on the information submitted by Greece, it is also not clear how the significant increase in air traffic controller numbers as well as subsequent on-the-job training from calendar year 2022 onwards will be managed while meeting increasing capacity demands.
- (57) Taking into account that Greece's draft capacity targets are higher than the corresponding national reference values during 2021-2024, it appears, in respect of point 2.1(a) of Annex IV to Implementing Regulation (EU) 2019/317, that the proposed measures will be insufficient to meet the expected traffic demand, particularly in light of expected traffic growth towards the end of RP3 as part of the air traffic recovery following the impact of the COVID-19 pandemic.
- (58) Greece states in its draft performance plan that the targets for calendar years 2021-2024 could not be set in line with the reference values included in the Network Operations Plan of September 2021 because of the more optimistic recovery of air traffic included in the October 2021 STATFOR traffic forecast. Greece further states that the proposed targets reflect this change of traffic assumptions and therefore deviate from the reference values.
- (59) However, in the light of the assessment criteria set out in point 1.3 to Annex IV to Implementing Regulation (EU) 2019/317, the Commission considers that the information and evidence provided by Greece in its draft performance plan, including in respect of relevant local circumstances, do not justify the proposed significant deviations of *en route* capacity targets from the corresponding reference values.
- (60) On the basis of the findings set out in recitals 53 to 59, the proposed targets included in the draft performance plan of Greece should be assessed as inconsistent with the Union-wide performance targets in the key performance area of capacity.

Review of draft capacity targets for terminal air navigation services

- (61) The Commission has concerns as regards the draft terminal capacity performance targets of Greece in accordance with point 2.1(b) of Annex IV to Implementing Regulation (EU) 2019/317.
- (62) Specifically, the Commission has found that when comparing at airport level the draft national targets on average arrival ATFM delay with the performance of similar airports, the airport of Athens is expected to experience higher ATFM delays than those forecasted for similar airports.
- (63) Therefore, the Commission considers that Greece should further justify the terminal capacity targets in light of the observations above, or should revise downwards the draft capacity targets for terminal air navigation services.

Assessment of draft performance targets in the key performance area of cost-efficiency

- (64) The draft *en route* cost-efficiency targets proposed by Greece are as follows:

<i>En route</i> charging zone of Greece	2014 baseline value	2019 baseline value	2020 -2021	2022	2023	2024
Draft <i>en route</i> cost-efficiency targets, expressed as determined <i>en route</i> unit cost (in real terms at 2017 prices)	31,37 EUR	23,20 EUR	40,71 EUR	32,60 EUR	33,12 EUR	32,93 EUR

- (65) As regards the criterion laid down in point 1.4(a) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that Greece's *en route* determined unit cost trend at charging zone level of +9,1 % over RP3 underperforms the Union-wide trend of +1,0 % over the same period.
- (66) As regards the criterion laid down in point 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that Greece's long-term *en route* determined unit cost trend at charging zone level over RP2 and RP3 of +0,5 % underperforms the long-term Union-wide trend of -1,3 % over the same period.
- (67) As regards the criterion laid down in point 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that Greece's baseline value for the determined unit cost of 23,20 EUR in EUR 2017 is 18,9 % lower than the average baseline value of EUR 28,59 in EUR2017 of the relevant comparator group. However, the Commission notes that the determined *en route* unit cost of Greece is planned to exceed the average of the comparator group during RP3, with a difference of +8,7 % observed in respect of calendar year 2024.
- (68) Furthermore, it is necessary to examine whether the deviations observed above from the criteria set out in points 1.4(a), 1.4(b) and 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317 may be deemed necessary and proportionate under point 1.4(d) of that Annex.
- (69) In respect of the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission notes that the difference estimated by the performance review body between the RP3 determined *en route* costs reported in Greece's draft performance plan and the determined costs that would be required to meet the RP3 Union-wide determined unit cost trend is approximately EUR 54 M in EUR2017, whilst a corresponding deviation from the long-term Union-wide trend amounts to EUR 31 M in EUR 2017.

- (70) Greece indicates in the draft performance plan that a significant increase in the number of air traffic controllers in operations at the Athens area control centre is foreseen in the course of RP3, resulting in a total of 71 additional full-time equivalents in 2024 as compared to 2019. Furthermore, several major investments regarding ATM and surveillance systems are planned to be realised towards the end of the reference period, with a significant cost impact from year 2022 onwards. Greece states in the draft performance plan that the related depreciation cost have been netted of amounts that were overcharged in RP2 in respect of delayed investments in fixed assets.
- (71) The Commission notes that the advice received from the performance review body points to ambiguities and inconsistencies as to the overall set of measures presented by Greece in respect of the implementation of its local capacity targets, leading the performance review body to question whether those measures will effectively be implemented and hence will have the expected impact. It should also be noted that Greece has neither detailed nor quantified, in its draft performance plan, the additional costs related to the training and recruitment of new air traffic controllers. In the absence of any substantiated information concerning those costs, the Commission estimates that both of the deviations referred to in recital 69 are too significant to justify that they could be exclusively attributed to measures for achieving the local capacity targets.
- (72) In addition, it should be noted that the draft capacity targets set by Greece have been found, for the reasons stated in recitals 53 to 59 of this Decision, to be inconsistent with the corresponding Union-wide targets. In the absence of capacity targets assessed as consistent, the Commission considers that at this stage it is not possible to conclude the assessment of the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317 in respect of Greece, as the planned measures required to achieve capacity targets may have to be amended in connection with the required revision of capacity targets.
- (73) Therefore, the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317 is not fulfilled in respect of Greece.
- (74) In respect of the criterion set out in point 1.4(d)(ii) of Annex IV to Implementing Regulation (EU) 2019/317, it suffices to mention that Greece has not presented in its draft performance plan any restructuring measures which would justify a deviation from the Union-wide determined unit cost trend or from the Union-wide long-term determined unit cost trend. Therefore, the criterion set out in point 1.4(d)(ii) is not fulfilled in respect of Greece.
- (75) In addition, the review of key factors and parameters referred to in point 2.1.(d) of Annex IV to Implementing Regulation (EU) 2019/317 underpinning the draft performance targets in the key performance area of cost-efficiency has resulted in the following findings regarding the proposed RP3 cost base of Greece.
- (76) The Commission notes that determined costs related to search and rescue have been added for the first time in the *en route* cost base of Greece in RP3. Those costs lead to a sizeable increase of the *en route* determined costs, and amount to approximately 9 % of the 2020 *en route* cost base and approximately 5 % of the 2024 total *en route* cost base. Greece should provide further justifications in its revised draft performance plan as to the eligibility and proportionality of the related determined costs and on their allocation between *en route* and terminal air navigation services, as well as between air navigation services and other relevant sectors.
- (77) Furthermore, the Commission takes note of the establishment of a new national supervisory authority organisationally separated from the air navigation service provider, which is associated with an increase of the supervision costs. Taking into account the magnitude of the related additional costs, Greece should further explain the underlying cost drivers and assumptions in its revised draft performance plan.
- (78) On the basis of the findings set out in recitals 64 to 77, the proposed targets included in the draft performance plan of Greece should be assessed as inconsistent with the Union-wide performance targets in the key performance area of cost-efficiency.

Review of draft cost-efficiency targets for terminal air navigation services

- (79) The Commission has concerns as regards the draft terminal cost-efficiency performance targets of Greece in accordance with point 2.1(c) of Annex IV to Implementing Regulation (EU) 2019/317.
- (80) The Commission observes that the draft targets for the terminal determined unit cost trend for Greece's terminal charging zone of +6,8 % over RP3 is higher than the actual terminal determined unit cost trend of -3,9 % observed over RP2.
- (81) Therefore, the Commission considers that Greece should further justify the terminal cost-efficiency targets in light of the observations above, or should revise downwards the draft targets for the terminal determined unit cost for RP3.

Review of the incentive schemes referred to in Article 11 of Implementing Regulation (EU) 2019/317 complementing the Commission's assessment of draft capacity targets

- (82) With regard to the elements for review set out in point 2.1 (f) of Annex IV to the Implementing Regulation (EU) 2019/317, the Commission observes that both the *en route* capacity incentive scheme and the terminal capacity incentive scheme proposed in Greece's draft performance plan comprise a maximum financial disadvantage amounting to 0,50 % of determined costs for *en route* and 0,60 % of determined costs for terminal, and a maximum financial advantage amounting to 0,10 % of determined costs for *en route* and 0,30 % of determined costs for terminal.
- (83) In respect of those incentive schemes, on the basis of expert advice provided by the performance review body, the Commission has strong doubts whether the proposed maximum financial disadvantage, which amounts to 0,50 % of determined costs for *en route* and 0,60 % of determined costs for terminal, would have any material impact on the revenue at risk, as required pursuant to Article 11(3), point (a), of Implementing Regulation (EU) 2019/317.
- (84) Therefore, Greece should revise its draft incentive schemes for achieving *en route* and terminal capacity targets so that the maximum financial disadvantages stemming from those incentive schemes are set at a level having a material impact on the revenue at risk, as expressly required under Article 11(3), point (a), of Implementing Regulation (EU) 2019/317, which in the Commission's view should lead to a maximum financial disadvantage equal to or higher than 1 % of determined costs.

FINDINGS CONCERNING CYPRUS

Assessment of draft performance targets in the key performance area of capacity

- (85) The draft capacity targets proposed by Cyprus, expressed in minutes of *en route* ATFM delay per flight, and the corresponding national reference values for RP3 set out in the Network Operations Plan of September 2021 are as follows:

	2021	2022	2023	2024
Draft <i>en route</i> capacity targets of Cyprus, in minutes of ATFM delay per flight	0,10	0,30	0,40	0,30
Reference values for Cyprus, in minutes of ATFM delay per flight	0,10	0,16	0,15	0,15

- (86) The Commission observes that the draft capacity targets proposed by Cyprus for calendar years 2021 to 2024 are higher than the corresponding national reference values set out in the Network Operations Plan of September 2021. In this respect, the greatest deviation of draft capacity targets from the corresponding national reference values are observed for the year 2024, followed by the targets for 2023 and 2022, respectively.

- (87) The Commission notes that the capacity enhancement measures which are outlined in the draft performance plan comprise some of the measures which have been set out in the Network Operations Plan of September 2021. Those measures include the enhancement of ATSP staffing levels, major investments into the upgrade of ATM infrastructure as well as airspace restructuring measures. Furthermore, as regards staffing, the number of air traffic controllers on duty in the Nicosia area control centre is planned to increase by 22 full-time equivalents over RP3.
- (88) However, the Commission observes that several relevant capacity enhancement measures which are contained in the Network Operations Plan of September 2021 are not included in the draft performance plan submitted by Cyprus, namely the improvement of air traffic flow and capacity management techniques, transition to the new area control centre and an operational excellence project.
- (89) Taking into account that Cyprus' draft capacity targets are higher than the corresponding national reference values during the last three calendar years of RP3, it appears, in respect of point 2.1(a) of Annex IV to Implementing Regulation (EU) 2019/317, that the proposed measures will be insufficient to meet the expected traffic demand, particularly in light of expected traffic growth over RP3.
- (90) Cyprus states in its draft performance plan that more ambitious targets could not be set due to cost-cutting measures to achieve targets in the cost-efficiency key performance area as well as the changing geopolitical situation which significantly impacts the provision of air navigation services.
- (91) However, in the light of the assessment criteria set out in point 1.3 of Annex IV to Implementing Regulation (EU) 2019/317, the Commission considers that the information and evidence provided by Cyprus in its draft performance plan, including in respect of relevant local circumstances, do not justify the proposed significant deviations of *en route* capacity targets from the corresponding reference values.
- (92) On the grounds of the findings set out in recitals 85 to 91, the proposed targets included in the draft performance plan of Cyprus should be assessed as inconsistent with the Union-wide performance targets in the key performance area of capacity.

Assessment of draft performance targets in the key performance area of cost-efficiency

- (93) The draft *en route* cost-efficiency targets proposed by Cyprus are as follows:

<i>En route</i> charging zone of Cyprus	2014 baseline value	2019 baseline value	2020 -2021	2022	2023	2024
Draft <i>en route</i> cost-efficiency targets, expressed as determined <i>en route</i> unit cost (in real terms at 2017 prices)	32,94 EUR	26,61 EUR	49,85 EUR	34,14 EUR	32,52 EUR	32,26 EUR

- (94) As regards the criterion laid down in point 1.4(a) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that Cyprus' *en route* determined unit cost trend at charging zone level of +4,9 % over RP3 underperforms the Union-wide trend of +1,0 % over the same period.
- (95) As regards the criterion laid down in point 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the long-term *en route* determined unit cost trend of Cyprus at charging zone level over RP2 and RP3 of -0,2 % per year underperforms the long-term Union-wide trend of -1,3 % over the same period.
- (96) As regards the criterion laid down in point 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that Cyprus' baseline value for the determined unit cost of EUR 26,61 in EUR 2017 is 4,7 % lower than the average baseline value of the relevant comparator group of EUR 27,91 in EUR 2017. However, the Commission notes that the determined *en route* unit cost of Cyprus is 6,0 % above the average of the comparator group in respect of year 2024.

- (97) Furthermore, it is necessary to examine whether the deviations observed above from the criteria set out in points 1.4(a) and 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317 may be deemed necessary and proportionate under point 1.4(d) of that Annex.
- (98) The Commission notes that the difference estimated by the performance review body between the RP3 determined *en route* costs reported in the draft performance plan of Cyprus and the determined costs that would be required to meet the RP3 Union-wide determined unit cost trend is approximately EUR 10 M in EUR2017, whilst a corresponding deviation from the long-term Union-wide trend amounts to approximately EUR 6 M in EUR 2017.
- (99) In respect of the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission notes that Cyprus has stated in its draft performance plan that the cost deviations from the Union-wide determined unit cost trend and from the long-term Union-wide determined unit cost trend are due to measures required to achieve capacity targets including enhanced staffing and the upgrade of the existing ATM system, which aim to enable the operation of additional ATC sectors. The draft performance plan indicates that additional air traffic controllers are expected to become operational during RP3, with the total number of air traffic controllers in operations planned to reach 100 full-time equivalents in 2024, up from 73 full-time equivalents in 2019. However, the Commission notes that Cyprus has not quantified in its draft performance plan the expected cost impact of the presented measures associated to the achievement of the local capacity targets.
- (100) It should be noted that the draft capacity targets set by Cyprus have been found, for the reasons stated in recitals 85 to 91, to be inconsistent with the corresponding Union-wide performance targets. In the absence of capacity targets assessed as consistent, the Commission considers that at this stage it is not possible to conclude the assessment relating to the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317 in respect of Cyprus, as the planned measures required to achieve capacity targets may be changed in connection with the required revision of capacity targets.
- (101) In respect of the criterion set out in point 1.4(d)(ii) of Annex IV to Implementing Regulation (EU) 2019/317, it should be noted that Cyprus refers in its draft performance plans to a planned restructuring measure consisting of the establishment of a new corporatized entity for the provision of air navigation services in Cyprus. Cyprus points out that it foresees restructuring costs in relation to that measure but also emphasises that the estimation of those costs was not possible at the time of establishing the draft performance plan. Accordingly, the draft performance plan does not contain any justification or details enabling the Commission to assess the applicability of the criterion set out in point 1.4(d)(ii) in respect of the notified measure. Consequently, the criterion set out in point 1.4(d)(ii) is not fulfilled in respect of Cyprus.
- (102) On the grounds of the findings set out in recitals 93 to 101, the proposed targets included in the draft performance plan of Cyprus should be assessed as inconsistent with the Union-wide performance targets in the key performance area of cost-efficiency.

FINDINGS CONCERNING LATVIA

Assessment of draft performance targets in the key performance area of cost-efficiency

- (103) The draft *en route* cost-efficiency targets proposed by Latvia for RP3 are as follows:

<i>En route</i> charging zone of Latvia	2014 baseline value	2019 baseline value	2020 -2021	2022	2023	2024
Draft <i>en route</i> cost-efficiency targets, expressed as determined <i>en route</i> unit cost (in real terms at 2017 prices)	27,90 EUR	23,61 EUR	40,07 EUR	31,28 EUR	29,14 EUR	26,83 EUR

- (104) As regards the criterion laid down in point 1.4(a) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the *en route* determined unit cost trend of Latvia at charging zone level of +3,3 % per year over RP3 underperforms the Union-wide trend of +1,0 % over the same period.
- (105) As regards the criterion laid down in point 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the long-term *en route* determined unit cost trend of Latvia at charging zone level over RP2 and RP3 of -0,4 % per year underperforms the long-term Union-wide trend of -1,3 % over the same period.
- (106) As regards the criterion laid down in point 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the baseline value for the determined unit cost of EUR 23,61 of Latvia in EUR2017 is 17,2 % lower than the average baseline value of EUR 28,51 in EUR2017 of the relevant comparator group. The Commission notes that the determined *en route* unit cost of Latvia for 2024 will continue to be lower by 15 % than the average of the comparator group.
- (107) Furthermore, it is necessary to examine whether the deviations observed above from the criteria set out in points 1.4(a) and 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317 may be deemed necessary and proportionate under point 1.4(d) of that Annex.
- (108) The Commission notes that the difference estimated by the performance review body between the RP3 determined *en route* costs reported in the draft performance plan of Latvia and the determined costs that would be required to meet the RP3 Union-wide determined unit cost trend is approximately EUR 2 M in EUR2017, whilst a corresponding deviation from the long-term Union-wide trend amounts to approximately EUR 2 M in EUR2017.
- (109) In respect of the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission notes that Latvia sets out in the draft performance plan certain measures undertaken by the air navigation service provider (LGS) for the purpose of achieving local capacity targets.
- (110) The Commission observes that following the implementation of cost cutting measures in 2020 and 2021, LGS intends to increase its staff and depreciation costs in the remaining RP3 years with a view to accommodating the traffic recovery expected from 2022 to 2024, and mitigating the increased workload due to re-routings around the Belarus airspace.
- (111) In relation to staffing measures, the Commission observes that LGS plans to increase the number of *en route* air traffic controllers in operation during RP3 by nine full-time-equivalents in 2020-2021, and one in 2022-2024. It is acknowledged that the ANSP set up this air traffic controller training programme before the pandemic, in order to accommodate predicted traffic growth and avoid future *en route* ATFM delays such as those experienced in RP2.
- (112) In relation to remuneration policy, the Commission observes that from 2022 LGS plans to restore some of its obligations towards employees, including an agreed 8 % gross salary raise which had been temporarily suspended during the crisis. In addition, Latvia expects to incur additional salary increases due to a general growth in the national average salary.
- (113) In relation to the planned investments in fixed assets, the Commission observes that LGS plans to resume various investment projects in RP3, subject to the financial performance of LGS and the actual traffic recovery. The Commission observes that the depreciation costs of the four 'new major investments' and 'other new investments' reported by LGS are expected to increase considerably in 2023. However, the contribution of those investments to the future capacity provision is not substantiated in the draft performance plan of Latvia.
- (114) The Commission acknowledges that employing additional air traffic controllers and resuming capacity-enhancing investments in fixed assets could be valid reasons to deviate from Union-wide DUC trends in order to deliver the necessary long-term capacity. However, the Commission could not establish, based on the information contained in the draft performance plan of Latvia, that the indicated increase in staff salaries would be a necessary and proportionate measure for achieving the local capacity performance targets and could be invoked to justify a deviation from the Union-wide DUC trends.

- (115) In addition, the Commission has found, on the basis of the assessment of the performance review body, that the cost of capital proposed by Latvia shows an anomaly in respect of the planned return on equity, which has not been set at a level commensurate with the financial risk exposure of the air navigation service provider. This leads over RP3 to a cost of capital which is approximately EUR 1,5 M higher than the financial risk incurred as a result of the traffic risk mechanism. That excess cannot be justified with reference to the achievement of capacity targets.
- (116) The Commission therefore considers that Latvia has not adequately demonstrated that the deviations referred to in recital 108 could be exclusively attributed to additional determined costs related to measures necessary to achieve the local performance targets in the key performance area of capacity. Therefore, the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317 is not fulfilled in respect of Latvia.
- (117) In respect of the criterion set out in point 1.4(d)(ii) of Annex IV to Implementing Regulation (EU) 2019/317, it suffices to mention that Latvia has not presented in the draft performance plan any restructuring measures which would justify a deviation from the Union-wide determined unit cost trend or from the Union-wide long-term determined unit cost trend. Therefore, the criterion set out in point 1.4(d)(ii) is not fulfilled in respect of Latvia.
- (118) In addition, the review of key factors and parameters referred to in point 2.1.(d) of Annex IV to Implementing Regulation (EU) 2019/317 underpinning the draft performance targets in the key performance area of cost-efficiency has resulted in the following findings related to the 2014 and 2019 baseline values and pension costs.
- (119) Firstly, the Commission observes that, from 2020, Latvia allocates a part of its cost base to the Vilnius flight information region ('Vilnius FIR') corresponding to the costs of ATM and communications, navigation, and surveillance (CNS) services provided in the NINTA – ADAXA route. However, the draft performance plan of Latvia reports baseline values that are equal to the 2014 and 2019 actual costs, respectively, without deducting the costs related to the NINTA – ADAXA route. Based on the advice of the performance review body, the Commission considers that the adjustments to the 2014 and 2019 cost and traffic baselines of Latvia are necessary in order to render those values comparable with the determined costs in RP3 and permit an accurate assessment of the RP3 cost-efficiency targets of Latvia.
- (120) Secondly, based on the advice of the performance review body, the Commission considers that Latvia should re-evaluate or better justify the proposed determined costs in respect of pensions, as the proportional share of those costs appears abnormally high in relation to the total cost base.
- (121) On the grounds of the findings set out in recitals 103 to 120, the proposed targets included in the draft performance plan of Latvia should be assessed as inconsistent with the Union-wide performance targets in the key performance area of cost-efficiency.

FINDINGS CONCERNING MALTA

Assessment of draft performance targets in the key performance area of cost-efficiency

- (122) The draft *en route* cost-efficiency targets proposed by Malta for RP3 are as follows:

<i>En route</i> charging zone of Malta	2014 baseline value	2019 baseline value	2020 -2021	2022	2023	2024
Draft <i>en route</i> cost-efficiency targets, expressed as determined <i>en route</i> unit cost (in real terms at 2017 prices)	21,50 EUR	22,98 EUR	44,08 EUR	31,85 EUR	24,83 EUR	24,85 EUR

- (123) As regards the criterion laid down in point 1.4(a) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the *en route* determined unit cost trend of Malta at charging zone level of +2,0 % per year over RP3 underperforms the Union-wide trend of +1,0 % over the same period.
- (124) As regards the criterion laid down in point 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the long-term *en route* determined unit cost trend of Malta at charging zone level over RP2 and RP3 of +1,6 % per year underperforms the long-term Union-wide trend of -1,3 % over the same period.
- (125) As regards the criterion laid down in point 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the baseline value for the determined unit cost of EUR 22,98 of Malta in EUR2017 is 19,7 % lower than the average baseline value of EUR 28,64 in EUR2017 of the relevant comparator group. The Commission notes that the determined *en route* unit cost of Malta for 2024 will continue to be lower by 22,1 % than the average of the comparator group.
- (126) Furthermore, it is necessary to examine whether the deviations observed above from the criteria set out in points 1.4 (a) and 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317 may be deemed necessary and proportionate under point 1.4(d) of that Annex.
- (127) The Commission notes that the difference estimated by the performance review body between the RP3 determined *en route* costs reported in the draft performance plan of Malta and the determined costs that would be required to meet the RP3 Union-wide determined unit cost trend is approximately EUR 1 M in EUR2017, whilst a corresponding deviation from the long-term Union-wide trend amounts to approximately EUR 5,8 M in EUR2017.
- (128) In respect of the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317, Malta has presented in its draft performance plan certain measures and investments related to the achievement of capacity targets.
- (129) In particular, the Commission observes that by 2024 MATSA plans to employ four technical specialists as air traffic safety electronics personnel and five air traffic controllers. The new air traffic controllers will however start with a Tower rating and the related staff costs are therefore planned to be initially mostly allocated to terminal air navigation services. The Commission also notes that, from 2023, MATSA plans to increase staff remunerations following a two-year salary freeze collectively agreed with its staff in order to save costs during the pandemic.
- (130) The Commission notes that MATSA plans to increase other operating costs for the purpose of improving staff competency and providing training in order to enable the delivery of future capacity. The Commission also observes that MATSA reports that higher insurance premiums and inflation are other key drivers of additional other operating costs.
- (131) The performance review body reports that MATSA plans to significantly increase its depreciation costs over RP3. However, the Commission received no evidence that the increase in depreciation costs can be justified due to capacity related measures, since the draft performance plan of Malta does not provide any details on the contribution to capacity of the new investments planned in RP3.
- (132) The Commission considers that an increase in the number of staff of the ANSP in order to accommodate future expected capacity could be a valid reason for a deviation under point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317 with regard to Malta. However, because of insufficient information in the draft performance plan, the Commission has not been able to establish whether the reported increases in staff salaries and the planned investments in fixed assets are necessary and proportionate in view of achieving the local capacity targets, and could hence be invoked to justify a deviation from the Union-wide DUC trends.
- (133) The Commission therefore considers that Malta has not adequately demonstrated that the deviations referred to in recitals 128 to 132 could be exclusively attributed to additional determined costs related to measures necessary to achieve the local performance targets in the key performance area of capacity. Consequently, the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317 is not fulfilled in respect of Malta.

- (134) In respect of the criterion set out in point 1.4(d)(ii) of Annex IV to Implementing Regulation (EU) 2019/317, it suffices to mention that Malta has not presented in the draft performance plan any restructuring measures which would justify a deviation from the Union-wide determined unit cost trend or from the Union-wide long-term determined unit cost trend. Therefore, the criterion set out in point 1.4(d)(ii) is not fulfilled in respect of Malta.
- (135) On the basis of the findings set out in recitals 122 to 134, the proposed targets included in the draft performance plan of Malta should be assessed as inconsistent with the Union-wide performance targets in the key performance area of cost-efficiency.

Review of draft cost-efficiency targets for terminal air navigation services

- (136) The Commission has concerns as regards the draft terminal cost-efficiency performance targets of Malta in accordance with point 2.1(c) of Annex IV to Implementing Regulation (EU) 2019/317.
- (137) Firstly, when comparing the RP3 terminal determined unit cost trend with the *en route* determined unit cost trend, the Commission has found that the terminal determined unit cost trend of Malta's terminal charging zone of +4,3 % is higher than Malta's *en route* determined unit cost trend at charging zone level of +2,0 % over RP3.
- (138) Secondly, the Commission observes that the draft targets for the terminal determined unit cost trend for Malta's terminal charging zone of +4,3 % over RP3 is higher than the actual terminal determined unit cost trend of +0,6 % observed over RP2.
- (139) Therefore, the Commission considers that Malta should further justify the terminal cost-efficiency targets in light of the observations above, or should revise downwards the draft targets for the terminal determined unit cost over RP3.

FINDINGS CONCERNING ROMANIA

Assessment of draft performance targets in the key performance area of cost-efficiency

- (140) The draft *en route* cost-efficiency targets proposed by Romania for RP3 are as follows:

<i>En route</i> charging zone of Romania	2014 baseline value	2019 baseline value	2020 -2021	2022	2023	2024
Draft <i>en route</i> cost-efficiency targets, expressed as determined <i>en route</i> unit cost (in real terms at 2017 prices)	165,00 RON	155,38 RON	298,87 RON	191,50 RON	174,25 RON	174,33 RON
	36,13 EUR	34,03 EUR	65,45 EUR	41,94 EUR	38,16 EUR	38,18 EUR

- (141) As regards the criterion laid down in point 1.4(a) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the *en route* determined unit cost trend of Romania at charging zone level of +2,9 % per year over RP3 underperforms the Union-wide trend of +1,0 % over the same period.
- (142) As regards the criterion laid down in point 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the long-term *en route* determined unit cost trend of Romania at charging zone level over RP2 and RP3 of +0,6 % per year underperforms the long-term Union-wide trend of -1,3 % over the same period.
- (143) As regards the criterion laid down in point 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the baseline value for the determined unit cost of EUR 34,03 of Romania in EUR2017 is 14,6 % lower than the average baseline value of EUR 39,84 in EUR2017 of the relevant comparator group. The Commission notes that the determined *en route* unit cost of Romania for 2024 will continue to be lower by 9,0 % than the average of the comparator group.

- (144) Furthermore, it is necessary to examine whether the deviations observed above from the criteria set out in points 1.4 (a) and 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317 may be deemed necessary and proportionate under point 1.4(d) of that Annex.
- (145) The Commission notes that the difference estimated by the performance review body between the RP3 determined *en route* costs reported in the draft performance plan and the determined costs that would be required to meet the RP3 Union-wide determined unit cost trend is approximately EUR 15 M in EUR2017, whilst a corresponding deviation from the long-term Union-wide trend amounts to approximately EUR 32 M in EUR2017.
- (146) In respect of the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission notes that Romania reports in the draft performance plan that additional determined costs will be incurred over RP3 by the *en route* air navigation service provider, namely ROMATSA, in order to implement measures to achieve the local capacity targets. The measures invoked by Romania relate mostly to staff and training costs, followed by investment costs.
- (147) The Commission observes that ROMATSA is planning to incur additional staff costs and other operating costs in order to recruit and train new *en route* air traffic controllers. Romania justifies the proposed recruitment and training plan in order to replace a large wave of planned retirements foreseen to peak in RP4. Romania points out that the plan shall start already in RP3 considering that it takes between three to five years to train a fully licenced air traffic controller. However, the performance review body found that the level of costs associated with the recruitment plan should be further substantiated and justified, considering their high level. On the basis of the advice of the performance review body, the Commission considers that ROMATSA should in particular provide further explanation on how the costs of staff and training per each full-time-equivalent have been calculated.
- (148) In relation to the investment costs, the Commission observes that the draft performance plan of Romania outlines the need to incur additional depreciation costs and cost of capital in order to implement the following projects: the ATM system step 1 phase 1 (which started in RP2 and depreciates from 2020) and step 1 phase 2 (which started in RP2 and depreciates from 2022), the traffic complexity and assessment tool planned to be implemented in 2024, and the Datalink service contract.
- (149) In respect of the ATM system costs, the performance review body had found in its RP2 monitoring report that the capital expenditure for step 1 phase 2 foreseen for RP2 was not realised over the whole reference period, and the total actual investment costs were significantly lower than those determined in the RP2 performance plan. Overall, the performance review body calculates that in RP2 airspace users have financed EUR 32,5 M for investments that have not been materialised, and it is unknown whether this amount will be reimbursed to airspace users. The performance review body concluded that the additional costs invoked by Romania as a deviation to achieve its local RP3 *en route* capacity targets are therefore not justified.
- (150) It should be noted that the Commission has found, based on the assessment of the performance review body, that the cost of capital proposed by Romania has not been set at a level commensurate with the efficient cost of capital level. This leads over RP3 to a cost of capital which is EUR 16 M higher than the financial risk incurred as a result of the traffic risk mechanism. That excess cannot be justified with reference to the achievement of capacity targets.
- (151) In light of the considerations set out in recitals 146 to 150 and having regard to the advice of the performance review body, the Commission concludes that the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317 is not fulfilled in respect of Romania.
- (152) In respect of the criterion set out in point 1.4(d)(ii) of Annex IV to Implementing Regulation (EU) 2019/317, it suffices to mention that Romania has not presented in the draft performance plan any restructuring measures which would justify a deviation from the Union-wide determined unit cost trend or from the Union-wide long-term determined unit cost trend. Therefore, the criterion set out in point 1.4(d)(ii) is not fulfilled in respect of Romania.

- (153) On the grounds of the findings set out in recitals 140 to 152, the proposed targets included in the draft performance plan of Romania should be assessed as inconsistent with the Union-wide performance targets in the key performance area of cost-efficiency.

Review of draft cost-efficiency targets for terminal air navigation services

- (154) The Commission has concerns as regards the draft terminal cost-efficiency performance targets of Romania in accordance with point 2.1(c) of Annex IV to Implementing Regulation (EU) 2019/317.
- (155) Firstly, when comparing the RP3 terminal determined unit cost trend with the *en route* determined unit cost trend, the Commission has found that the terminal determined unit cost trend of Romania's terminal charging zone of +4,3 % is higher than Romania's *en route* determined unit cost trend at charging zone level of +2,9 % over RP3.
- (156) Secondly, the Commission observes that the draft targets for the terminal determined unit cost trend for Romania's terminal charging zone of +4,3 % over RP3 is higher than the actual terminal determined unit cost trend of -3,1 % observed over RP2.
- (157) Therefore, the Commission considers that Romania should further justify the terminal cost-efficiency targets in light of the observations above, or should revise downwards the draft targets for the terminal determined unit cost for RP3.

Review of the incentive schemes referred to in Article 11 of Implementing Regulation (EU) 2019/317 complementing the Commission's assessment of draft capacity targets

- (158) With regard to the elements for review set out in point 2.1 (f) of Annex IV to the Implementing Regulation (EU) 2019/317, the Commission observes that the terminal capacity incentive scheme proposed in Romania's draft performance plan comprise a maximum financial disadvantage amounting to 0,50 % of determined costs and a maximum financial advantage amounting to 0,50 % of determined costs.
- (159) In respect of the terminal incentive scheme, on the basis of expert advice provided by the performance review body, the Commission has strong doubts whether the proposed maximum financial disadvantage, which amounts to 0,50 % of determined costs, would have any material impact on the revenue at risk, as required pursuant to Article 11(3), point (a), of Implementing Regulation (EU) 2019/317.
- (160) Therefore, Romania should revise its draft incentive scheme for achieving terminal capacity targets so that the maximum financial disadvantage stemming from that incentive scheme is set at a level having a material impact on the revenue at risk, as expressly required under Article 11(3), point (a), of Implementing Regulation (EU) 2019/317, which in the Commission's view should lead to a maximum financial disadvantage equal to or higher than 1 % of determined costs.

FINDINGS CONCERNING SWEDEN

Assessment of draft performance targets in the key performance area of cost-efficiency

- (161) The draft *en route* cost-efficiency targets proposed by Sweden for RP3 are as follows:

<i>En route</i> charging zone of Sweden	2014 baseline value	2019 baseline value	2020 -2021	2022	2023	2024
Draft <i>en route</i> cost-efficiency targets, expressed as determined <i>en route</i> unit cost (in real terms at 2017 prices)	522,30 SEK	567,11 SEK	1 361,88 SEK	676,24 SEK	605,51 SEK	570,87 SEK
	54,22 EUR	58,87 EUR	141,38 EUR	70,20 EUR	62,86 EUR	59,26 EUR

- (162) As regards the criterion laid down in point 1.4(a) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the *en route* determined unit cost trend of Sweden at charging zone level of +0,2 % per year over RP3 outperforms the Union-wide trend of +1,0 % over the same period.
- (163) As regards the criterion laid down in point 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the long-term *en route* determined unit cost trend of Sweden at charging zone level over RP2 and RP3 of +1,0 % per year underperforms the long-term Union-wide trend of -1,3 % over the same period.
- (164) As regards the criterion laid down in point 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the baseline value for the determined unit cost of EUR 58,87 of Sweden in EUR2017 is 31,6 % higher than the average baseline value of EUR 44,74 in EUR2017 of the relevant comparator group. The Commission notes that that difference becomes even larger during RP3, as the determined *en route* unit cost of Sweden for 2024 is higher by 41,8 % than the average of the comparator group.
- (165) It is necessary to examine whether the deviations observed above from the criteria set out in points 1.4(b) and 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317 may be deemed necessary and proportionate under point 1.4(d) of that Annex.
- (166) The Commission notes that the difference estimated by the performance review body between the RP3 determined *en route* costs reported in the draft performance plan of Sweden and the determined costs that would be required to meet the long-term Union-wide trend amounts to approximately EUR 43 M in EUR2017.
- (167) In respect of the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission notes that Sweden presents in the draft performance plan several measures related to the achievement of local capacity targets.
- (168) In particular, the Commission observes that the main *en route* air navigation service provider, namely LFV, is planning to train new air traffic controllers to address upcoming retirements in the remaining RP3 years. Sweden reports a planned net increase during RP3 of 14 full-time-equivalent air traffic controllers in the area control centre in Malmö and 14 full-time-equivalent air traffic controllers in the area control centre in Stockholm. However, the Commission notes that Sweden has not quantified the expected cost impact of those staff-related measures in its draft performance plan.
- (169) The Commission observes that, in addition to staff costs, Sweden reports that the largest new major investment of LFV is the 'expansion of remote tower services' in Stockholm and four connected airports (Kiruna, Umeå, Östersund, Malmö). The determined costs of the 'expansion of remote tower services' amount to 11 % of the total determined costs of investments over RP3. The Commission notes that in general remote towers are investments that provide air traffic services at airports and should therefore, in principle, be mainly allocated to terminal services. However, the draft performance plan of Sweden allocates 75 % of the costs of the 'expansion of remote tower services' to *en route* services without giving a justification on the geographic scope and the nature of the services. The Commission also observes that airspace users questioned the business case of this investment during consultations. The Commission considers that Sweden should revise or further justify the business case and the cost allocation of this investment, and should address the concerns expressed by airspace users.
- (170) The Commission notes that the other new investments planned by Sweden amount to 33 % of the total determined costs of investments over RP3. The draft performance plan of Sweden mentions that other new investments consist of replacements and/or upgrades related to communication systems, radio, navigational aids, as well as fallback and support systems for ATS. However, the Commission notes that the draft performance plan of Sweden does not provide information on how each of these other new investments will contribute to achieve the local capacity targets.
- (171) In light of the considerations set out in recitals 167 to 170, the Commission considers that Sweden has not adequately demonstrated that the deviation referred to in recital 166 could be exclusively attributed to additional determined costs related to measures necessary to achieve the local capacity performance targets. Therefore, the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317 is not fulfilled in respect of Sweden.

- (172) In respect of the criterion set out in point 1.4(d)(ii) of Annex IV to Implementing Regulation (EU) 2019/317, it suffices to mention that Sweden has not presented in the draft performance plan any restructuring measures which would justify a deviation from the Union-wide determined unit cost trend or from the Union-wide long-term determined unit cost trend. Therefore, the criterion set out in point 1.4(d)(ii) is not fulfilled in respect of Sweden.
- (173) In addition, the review of key factors and parameters referred to in point 2.1.(d) of Annex IV to Implementing Regulation (EU) 2019/317 underpinning the draft performance targets in the key performance area of cost-efficiency has resulted in the following findings related to the 2019 cost baseline, the cost of capital and pensions.
- (174) The Commission observes that Sweden proposes to adjust the 2019 baseline to account for the introduction of three new airports in the system of *en route* charges from 2020 onwards. The performance review body notes that the majority of this adjustment relates to the Scandinavian Mountain Airport where the ANSP SDATS provides ATC services. The draft performance plan reports that many Swedish airports provide *en route* services. Sweden indicates that allowing airports to provide *en route* and approach services is more cost-efficient because terminal manoeuvring areas in Swedish airports are large and geographically distant.
- (175) The draft performance plan of Sweden indicates that the inclusion of the three new airports in the *en route* scheme does not transfer responsibilities or costs between the ANSPs already included in the scheme. The performance review body found that this adjustment is not clearly explained in the draft performance plan of Sweden.
- (176) On the basis of the advice of the performance review body, the Commission considers that Sweden should re-evaluate the amounts proposed to be charged as return on equity within the cost of capital for LFV. The performance review body estimates that, over RP3, the reported cost of capital is EUR 1,3 M above the efficient cost of capital. Specifically, the Commission and the performance review body observe that the cost of equity range proposed by Sweden for LFV amounting to 0,7 % – 1,9 % is higher than the cost of equity allowed by the Swedish Government for LFV amounting to 0,0 %. The Commission notes that the proposed cost of capital of LFV includes a return on equity of a number of Swedish airports which provide *en route* services. The Commission considers that Sweden should clarify and justify the inclusion of these airports in all the cost items of LFV, or else revise its submission accordingly.
- (177) On the basis of the advice of the performance review body, the Commission considers that Sweden should re-evaluate the proposed pension costs. The performance review body found that the average share of pension costs of LFV over RP3 is significantly higher than the Union-wide average. It also found that the contributions associated with the public pension scheme are included in staff costs as social security costs rather than in the pension costs identified separately in the reporting tables. The performance review body indicates that pension costs are also recorded in the cost of capital since outstanding receivables related to pension costs from previous reference periods are included in the asset base. The performance review body concludes that the lack of transparency in the defined benefit scheme assumptions could become an issue for the verification of RP3 costs exempt. The Commission considers that Sweden should transparently report the pension costs in the separate pension costs line of the reporting tables.
- (178) On the basis of the findings set out in recitals 161 to 177, the proposed targets included in the draft performance plan of Sweden should be assessed as inconsistent with the Union-wide performance targets in the key performance area of cost-efficiency.

Review of draft cost-efficiency targets for terminal air navigation services

- (179) The Commission has concerns as regards the draft terminal cost-efficiency performance targets of Sweden in accordance with point 2.1(c) of Annex IV to Implementing Regulation (EU) 2019/317.
- (180) Firstly, when comparing the RP3 terminal determined unit cost trend with the *en route* determined unit cost trend, the Commission has found that the terminal determined unit cost trend of Sweden's terminal charging zone of +0,9 % is higher than Sweden's *en route* determined unit cost trend at charging zone level of +0,2 % over RP3.

- (181) Secondly, the Commission observes that the draft targets for the terminal determined unit cost trend for Sweden's terminal charging zone of +0,9 % over RP3 is higher than the actual terminal determined unit cost trend of -5,8 % observed over RP2.
- (182) Thirdly, when comparing the draft national targets of the terminal determined unit cost trend with the performance of similar airports for RP3, the Commission observes that the determined unit cost for Stockholm Arlanda Airport is estimated to be above the median determined unit cost of the relevant comparator group by a limited margin.
- (183) Therefore, the Commission considers that Sweden should further justify the terminal cost-efficiency targets in light of the observations above, or should revise downwards the draft targets for the terminal determined unit cost for RP3.

CONCLUSIONS

- (184) On the basis of the assessment set out in recitals 21 to 183, the Commission has found that the draft national and functional airspace block performance plans submitted by Belgium, Germany, Greece, France, Cyprus, Latvia, Luxembourg, Malta, the Netherlands, Romania, and Sweden contain certain performance targets which are not consistent with the Union-wide performance targets.
- (185) In accordance with Article 14(3) of Implementing Regulation (EU) 2019/317, the Member States concerned are to submit their revised draft performance plans to the Commission within three months from the date of the adoption of this Decision, taking account of the recommendations put forward by the Commission.
- (186) Belgium, France, Germany, Luxembourg, the Netherlands, which together with Switzerland developed and submitted a draft RP3 performance plan at FAB level, should jointly submit a revised draft performance plan for FABEC addressing the recommendations set out in this Decision.
- (187) The Commission will subsequently assess the revised draft performance plans in their entirety in accordance with the procedure set out in Article 15 of Implementing Regulation (EU) 2019/317 and, as a result of that subsequent assessment, the Commission can take any position in respect of the draft performance targets and other elements of the performance plans for which no objections were raised in this Decision.
- (188) Pursuant to Article 17 of Implementing Regulation (EU) 2019/317, the targets set in the most recent version of the draft performance plan are to apply on a provisional basis until the Commission has made a decision on the consistency of performance targets or revised performance targets, after which the Member State or Member States concerned are required to adopt their final performance plan.
- (189) In respect of the key performance area of cost-efficiency, Article 17 of Implementing Regulation (EU) 2019/317 has conferred a retroactive effect to the targets contained in the final performance plan. As a result, any difference in revenue due to the application of the unit rate or unit rates calculated on the basis of the draft performance plan, instead of the unit rate or unit rates calculated on the basis of the final performance plan, will be settled through subsequent unit rate adjustments during RP3 which are further regulated by the exceptional measures for RP3 set out in Implementing Regulation (EU) 2020/1627. Therefore, the Commission will not conclude on the compliance of the unit rates in accordance with Article 29(3) of Implementing Regulation (EU) 2019/317 before the relevant final performance plans have been adopted.
- (190) The Commission notes that some Member States have indicated their intention to include cost items relating to airport drone detection in their RP3 cost bases. It has not been possible to precisely establish, based on the elements contained in the draft performance plans, to what extent Member States have included such determined costs in their RP3 cost bases and, where such costs have been included, to what extent they are incurred in relation to the provision of air navigation services and could thus be deemed eligible under the performance and charging scheme. The Commission services have sent an ad hoc information request to all Member States in order to gather relevant information, and will further examine the reported airport drone detection costs in the context of unit rate compliance verification. This Decision is without prejudice to the findings and conclusions of the Commission on the topic of drone detection costs.

(191) In response to Russia's military aggression against Ukraine, which started on 24 February 2022, the Union has adopted restrictive measures prohibiting Russian air carriers, any Russian-registered aircraft and any non-Russian-registered aircraft which is owned or chartered, or otherwise controlled by any Russian natural or legal person, entity or body from landing in, taking off from, or overflying the territory of the Union. Those measures are leading to a reduced air traffic in the airspace over the territory of the Union. The impact at the Union-wide level should however not be comparable to the reduction of air traffic which resulted from the outbreak of the COVID-19 pandemic in March 2020. Therefore, it is appropriate to maintain the existing measures and processes for the implementation of the performance and charging scheme in RP3. When revising their local performance targets as part of the revised draft performance plans, Member States to whom this Decision is addressed should take due account of the operational and financial effects of relevant changes in traffic,

HAS ADOPTED THIS DECISION:

Article 1

The performance targets contained in the draft national and functional airspace block performance plans submitted by Belgium, Germany, Greece, France, Cyprus, Latvia, Luxembourg, Malta, the Netherlands, Romania, and Sweden pursuant to Regulation (EC) No 549/2004, listed in the Annex to this Decision, are inconsistent with the Union-wide performance targets for the third reference period ('RP3') set out in Implementing Decision (EU) 2021/891.

Article 2

Cyprus and Greece shall revise downwards their draft en route capacity targets, expressed as the average minutes of en route air traffic flow management delay per flight.

The Member States concerned shall address the observed deviations between the submitted draft capacity targets and the corresponding reference values set out in the Network Operations Plan of September 2021 in respect of calendar years 2022, 2023 and 2024 of RP3 in order to accommodate the anticipated traffic demand. Where the Network Operations Plan recommends specific measures to improve capacity performance, account shall be taken of those measures when revising the performance targets.

Article 3

Belgium, Greece, Cyprus, Latvia, Luxembourg, Malta, Romania, and Sweden shall revise downwards the draft cost-efficiency targets set for their *en route* charging zones, expressed as determined unit cost (DUC).

When revising their draft cost-efficiency targets, all the Member States concerned shall:

- (a) ensure that the revised cost-efficiency targets are consistent both with the Union-wide DUC trend and with the Union-wide long-term DUC trend;
- (b) reduce the level of determined costs accordingly, at least in respect of calendar year 2024;
- (c) use the latest traffic forecasts, expressed in service units, in accordance with Article 10(2) of Implementing Regulation (EU) 2019/317.

By way of derogation from point (a), where the Commission has found in this Decision that the baseline value of the relevant *en route* charging zone fulfils the criterion laid down in point 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317, the Member State concerned shall ensure that the revised cost-efficiency targets are consistent at least with the Union-wide DUC trend or with the Union-wide long-term DUC trend.

Where a Member State invokes in its revised draft performance plan a deviation under point 1.4(d) of Annex IV to Implementing Regulation (EU) 2019/317, it shall ensure that such a deviation is substantiated with adequate information and justifications.

Article 4

This Decision is addressed to the Kingdom of Belgium, the Federal Republic of Germany, the Hellenic Republic, the French Republic, the Republic of Cyprus, the Republic of Latvia, the Grand Duchy of Luxembourg, the Republic of Malta, the Kingdom of the Netherlands, Romania, and the Kingdom of Sweden.

Done at Brussels, 13 April 2022.

For the Commission

Adina VĂLEAN

Member of the Commission

ANNEX

Performance targets included in the national or functional airspace block plans submitted pursuant to Regulation (EC) No 549/2004 found to be inconsistent with the Union-wide performance targets for the third reference period

1. TARGETS CONTAINED IN THE DRAFT PERFORMANCE PLAN OF FABEC

KEY PERFORMANCE AREA OF COST-EFFICIENCY**Determined unit cost for en route air navigation services**

En route charging zone of Belgium and Luxemboug	2014 baseline value	2019 baseline value	2020- 2021	2022	2023	2024
Draft en route cost-efficiency targets , expressed as determined en route unit cost (in real terms at 2017 prices)	73,13 EUR	83,28 EUR	189,52 EUR	113,26 EUR	108,51 EUR	103,82 EUR

2. TARGETS CONTAINED IN THE DRAFT PERFORMANCE PLAN OF GREECE

KEY PERFORMANCE AREA OF CAPACITY**Average en route Air Traffic Flow Management delay in minutes per fight**

	2021	2022	2023	2024
Draft en route capacity targets of Greece	0,32	0,26	0,20	0,20
Reference values for Greece	0,10	0,14	0,15	0,15

KEY PERFORMANCE AREA OF COST-EFFICIENCY**Determined unit cost for en route air navigation services**

En route charging zone of Greece	2014 baseline value	2019 baseline value	2020- 2021	2022	2023	2024
Draft en route cost-efficiency targets , expressed as determined en route unit cost (in real terms at 2017 prices)	31,37 EUR	23,20 EUR	40,71 EUR	32,60 EUR	33,12 EUR	32,93 EUR

3. TARGETS CONTAINED IN THE DRAFT PERFORMANCE PLAN OF CYPRUS

KEY PERFORMANCE AREA OF CAPACITY

Average en route Air Traffic Flow Management delay in minutes per flight

	2021	2022	2023	2024
Draft en route capacity targets of Cyprus	0,10	0,30	0,40	0,30
Reference values for Cyprus	0,10	0,16	0,15	0,15

KEY PERFORMANCE AREA OF COST-EFFICIENCY

Determined unit cost for en route air navigation services

En route charging zone of Cyprus	2014 baseline value	2019 baseline value	2020 -2021	2022	2023	2024
Draft en route cost-efficiency targets, expressed as determined en route unit cost (in real terms at 2017 prices)	32,94 EUR	26,61 EUR	49,85 EUR	34,14 EUR	32,52 EUR	32,26 EUR

4. TARGETS CONTAINED IN THE DRAFT PERFORMANCE PLAN OF LATVIA

KEY PERFORMANCE AREA OF COST-EFFICIENCY

Determined unit cost for en route air navigation services

En route charging zone of Latvia	2014 baseline value	2019 baseline value	2020 -2021	2022	2023	2024
Draft en route cost-efficiency targets, expressed as determined en route unit cost (in real terms at 2017 prices)	27,90 EUR	23,61 EUR	40,07 EUR	31,28 EUR	29,14 EUR	26,83 EUR

5. TARGETS CONTAINED IN THE DRAFT PERFORMANCE PLAN OF MALTA

KEY PERFORMANCE AREA OF COST-EFFICIENCY

Determined unit cost for en route air navigation services

En route charging zone of Malta	2014 baseline value	2019 baseline value	2020-2- 021	2022	2023	2024
Draft en route cost-efficiency targets, expressed as determined en route unit cost (in real terms at 2017 prices)	21,50 EUR	22,98 EUR	44,08 EUR	31,85 EUR	24,83 EUR	24,85 EUR

6. TARGETS CONTAINED IN THE DRAFT PERFORMANCE PLAN OF ROMANIA

KEY PERFORMANCE AREA OF COST-EFFICIENCY

Determined unit cost for en route air navigation services

En route charging zone of Romania	2014 baseline value	2019 baseline value	2020 -2021	2022	2023	2024
Draft en route cost-efficiency targets, expressed as determined en route unit cost (in real terms at 2017 prices)	165,00 RON	155,38 RON	298,87 RON	191,50 RON	174,25 RON	174,33 RON
	36,13 EUR	34,03 EUR	65,45 EUR	41,94 EUR	38,16 EUR	38,18 EUR

7. TARGETS CONTAINED IN THE DRAFT PERFORMANCE PLAN OF SWEDEN

KEY PERFORMANCE AREA OF COST-EFFICIENCY

Determined unit cost for en route air navigation services

En route charging zone of Sweden	2014 baseline value	2019 baseline value	2020 -2021	2022	2023	2024
Draft en route cost-efficiency targets, expressed as determined en route unit cost (in real terms at 2017 prices)	522,30 SEK	567,11 SEK	1 361,88 SEK	676,24 SEK	605,51 SEK	570,87 SEK
	54,22 EUR	58,87 EUR	141,38 EUR	70,20 EUR	62,86 EUR	59,26 EUR

COMMISSION IMPLEMENTING DECISION (EU) 2022/729**of 11 May 2022****amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for quality management systems and for application of risk management to medical devices**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ⁽¹⁾, and in particular Article 10(6) thereof,

Whereas:

- (1) In accordance with Article 8(1) of Regulation (EU) 2017/746 of the European Parliament and of the Council ⁽²⁾, devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, are to be presumed to be in conformity with the requirements of that Regulation covered by those standards or parts thereof.
- (2) Regulation (EU) 2017/746 will replace Directive 98/79/EC of the European Parliament and of the Council ⁽³⁾ from 26 May 2022.
- (3) By Implementing Decision C(2021) 2406 ⁽⁴⁾, the Commission made a request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) for the revision of existing harmonised standards on *in vitro* diagnostic medical devices developed in support of Directive 98/79/EC and the drafting of new harmonised standards in support of Regulation (EU) 2017/746.
- (4) On the basis of the request set out in Implementing Decision C(2021) 2406, CEN and Cenelec revised harmonised standard EN ISO 14971:2019, the reference of which is not published in the *Official Journal of the European Union*, in order to take into account the latest technical and scientific progress and to adapt it to the requirements of Regulation (EU) 2017/746. This resulted in the adoption of the amendment EN ISO 14971:2019/A11:2021 to harmonised standard EN ISO 14971:2019 on application of risk management to medical devices.
- (5) The Commission together with CEN and Cenelec has assessed whether the harmonised standard EN ISO 14971:2019, as amended by EN ISO 14971:2019/A11:2021, complies with the request set out in Implementing Decision C(2021) 2406.
- (6) Harmonised standard EN ISO 14971:2019, as amended by EN ISO 14971:2019/A11:2021, satisfies the requirements which it aims to cover and which are set out in Regulation (EU) 2017/746. It is therefore appropriate to publish the reference of harmonised standard EN ISO 14971:2019 and of its amendment in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 316, 14.11.2012, p. 12.

⁽²⁾ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

⁽³⁾ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

⁽⁴⁾ Commission Implementing Decision C(2021) 2406 of 14 April 2021 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council.

- (7) The Annex to Commission Implementing Decision (EU) 2021/1195 ^(*) lists the references of harmonised standards drafted in support of Regulation (EU) 2017/746.
- (8) In order to ensure that the references of harmonised standards drafted in support of Regulation (EU) 2017/746 are listed in one act, the reference of harmonised standard EN ISO 14971:2019 and of its amendment should be included in Implementing Decision (EU) 2021/1195.
- (9) The references of harmonised standard EN ISO 13485:2016 on quality management systems and its amendment EN ISO 13485:2016/A11:2021 are published by Implementing Decision (EU) 2021/1195. However, that publication does not include the reference of the corrigendum to that standard – EN ISO 13485:2016/AC:2018. The corrigendum corrects only formal aspects of the European foreword and of the informative annexes, without affecting the substance of the harmonised standard. Harmonised standard EN ISO 13485:2016 as amended by EN ISO 13485:2016/A11:2021 and corrected by EN ISO 13485:2016/AC:2018 satisfies the requirements which it aims to cover and which are set out in Regulation (EU) 2017/746. In order to ensure that corrections made by EN ISO 13485:2016/AC:2018 apply for the purposes of the presumption of conformity with the relevant requirements of Regulation (EU) 2017/746, it is necessary to include the reference of that corrigendum in Implementing Decision (EU) 2021/1195. For reasons of legal certainty, the reference of corrigendum EN ISO 13485:2016/AC:2018 should be published in the *Official Journal of the European Union* with retroactive effect.
- (10) Implementing Decision (EU) 2021/1195 should therefore be amended accordingly.
- (11) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the day of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision (EU) 2021/1195 is amended in accordance with the Annex to this Decision.

Article 2

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

Point 1 of the Annex shall apply from 7 January 2022.

Done at Brussels, 11 May 2022.

For the Commission
The President
Ursula VON DER LEYEN

^(*) Commission Implementing Decision (EU) 2021/1195 of 19 July 2021 on the harmonised standards for *in vitro* diagnostic medical devices drafted in support of Regulation (EU) 2017/746 of the European Parliament and of the Council (OJ L 258, 20.7.2021, p. 50).

ANNEX

The Annex to Implementing Decision (EU) 2021/1195 is amended as follows:

(1) entry No 7 is replaced by the following:

No	Reference of the standard
'7.	EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021';

(2) the following entry is added:

No	Reference of the standard
'10.	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021'.

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN