



European Aviation Safety Agency
Explanatory Note to Decision 2018/012/R

Aircrew medical fitness

RELATED OPINION NO 14/2016 — RMT.0700

EXECUTIVE SUMMARY

This Decision is associated with the amendments introduced through Regulation (EU) 2018/1042 of 23 July 2018 to Regulation (EU) No 965/2012 as regards technical requirements and administrative procedures related to introducing support programmes, psychological assessment of flight crew, as well as systematic and testing of psychoactive substances to ensure medical fitness of air crew.

This Decision addresses the safety issues identified pertaining to air crew medical fitness by the EASA-led Germanwings Task Force (hereinafter referred to as the ‘Task Force’) following the accident of Germanwings Flight 9525.

Finally, this Decision addresses the safety recommendations made in the final accident investigation report (March 2016) by the French Bureau d’Enquêtes et d’Analyses pour la Sécurité de l’Aviation Civile (BEA).

It contains new Guidance Material to Regulation (EU) No 965/2012, as well as Acceptable Means of Compliance and Guidance Material to Part-ARO and Part-CAT. The changes introduced by this Decision can be summarised as follows:

- (a) Preventive, corrective and follow-up measures such as:
 - (1) psychological assessment of flight crew before commencing line flying;
 - (2) enabling, facilitating and ensuring access to a support programme for flight crew; and
 - (3) systematic testing of psychoactive substances upon employment and with due cause.
- (b) As a complementary measure: risk-based alcohol testing of flight and cabin crew of European and third-country operators by Member States at European airports to ensure an additional safety barrier.

The proposed changes are expected to enhance safety.

Action area:	Human factors and competence of personnel		
Affected rules:	GM to Regulation (EU) No 965/2012; AMC and GM to Part-ARO; AMC and GM to Part-CAT.		
Affected stakeholders:	Pilots, cabin crew, competent authorities and European and third-country CAT operators		
Driver:	Safety	Rulemaking group:	No
Impact assessment:	Full	Rulemaking Procedure:	Special (Article 15 ‘Direct publication’)

• EASA special rulemaking procedure milestones

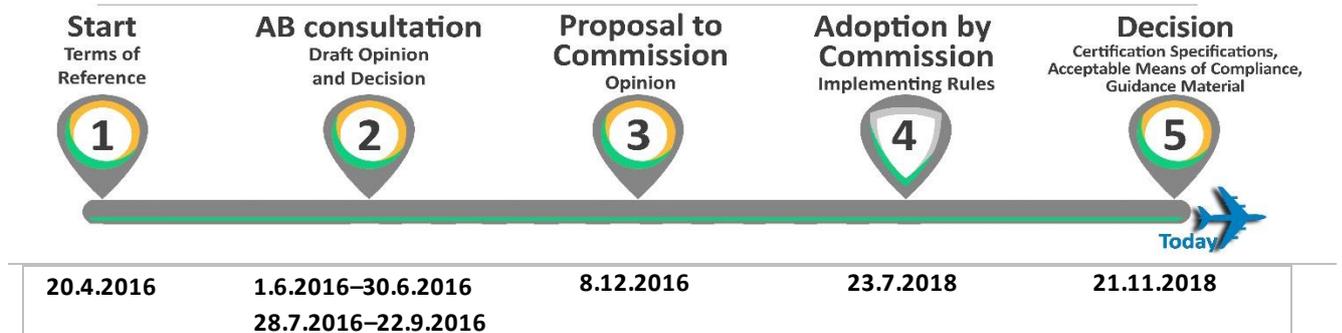


Table of contents

1. About this Decision.....	3
2. In summary — why and what.....	5
2.1. Why we need to change the AMC & GM	5
2.2. What we want to achieve — objectives.....	5
2.3. How we want to achieve it — overview of the proposals.....	6
2.4. How we address safety recommendations (SRs)	7
3. References	10
3.1. Related regulations.....	10
3.2. Affected decisions.....	10



1. About this Decision

The European Aviation Safety Agency (EASA) developed ED Decision 2018/012R in line with Regulation (EU) 2018/1139¹ (hereinafter referred to as the 'Basic Regulation') and the Rulemaking Procedure².

This rulemaking activity is included in the EASA European Plan for Aviation Safety (EPAS)³ under rulemaking task (RMT).0700. The scope and timescales of the task were defined in the related Terms of Reference⁴. The publication of the ToR for RMT.0700 was the outcome of a set of preliminary consultation activities carried out by EASA in the period from November 2015 until February 2016. These activities include the:

- (a) publication on the EASA website of preliminary concept papers on how to address the recommendations of the Task Force. The objective of this publication was to provide for a more focused discussion during the Aircrew Medical Fitness workshop (see point (b));
- (b) Aircrew Medical Fitness workshop on 7 and 8 December 2015; and
- (c) 4-week Advisory Bodies' consultation (January–February 2016) of the final concept papers addressing the feedback received by the aviation community during the Aircrew Medical Fitness workshop.

As no rulemaking group was set up for this rulemaking task, EASA organised a technical meeting on 9 and 10 May 2016 with a number of representatives of the affected stakeholders. This allowed EASA to have a technical discussion during the drafting of the regulatory text and thus have immediate technical feedback on the elements of the draft implementing rules and the draft Decision.

Following the technical meeting, the resulting regulatory material was consulted with the EASA Advisory Bodies from 1 to 30 June 2016 and during the Aircrew EASA Action Plan Conference held on 15 and 16 June 2016.

The Conference, attended by more than 130 participants, provided EASA with the opportunity to receive valuable input. In addition to written feedback from national aviation authorities (NAAs), airlines, as well as European industry and flight crew associations and medical associations during the Advisory Bodies' consultation on the changes proposed in June 2016 to Commission Regulation (EU) No 965/2012⁵ ('the Air OPS rules regulation) and the proposed acceptable means of compliance (AMC) and guidance material (GM).

¹ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1536149403076&uri=CELEX:32018R1139>)

² EASA is bound to follow a structured rulemaking process as required by Article 115(1) of Regulation (EU) 2018/1139. Such a process has been adopted by the EASA Management Board (MB) and is referred to as the 'Rulemaking Procedure'. See MB Decision No 18-2015 of 15 December 2015 replacing Decision 01/2012 concerning the procedure to be applied by EASA for the issuing of opinions, certification specifications and guidance material (<http://www.easa.europa.eu/the-agency/management-board/decisions/easa-mb-decision-18-2015-rulemaking-procedure>).

³ https://www.easa.europa.eu/document-library/general-publications?publication_type%5B%5D=2467

⁴ <https://www.easa.europa.eu/document-library/terms-of-reference-and-group-compositions/tor-rmt0700>

⁵ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the

An additional consultation of the proposed changes to the Air OPS rules and the draft Decision, including a proposal to implement alcohol testing by Member States, was carried out from 28 July to 22 September 2016.

As the comments on the topic of alcohol testing received during the consultation that ended on 22 September 2016 were quite heterogeneous, an additional technical meeting with the commentators took place on 3 November 2016.

Following discussions with the Member States after the publication of Opinion No 14-2016⁶ and the adoption of the Opinion (through Regulation (EU) 2018/1042⁷ that amended Regulation (EU) No 965/2012⁸), EASA further consulted with stakeholders on a revised version of the draft Decision with the support of an NAA expert group⁹. Furthermore, after the publication of Regulation (EU) 2018/1042, all interested parties, including EASA Advisory Bodies, were consulted through a dedicated focused consultation¹⁰.

This final consultation from July 2018 to September 2018 allowed stakeholders to take into account the implementing rules (IRs) as published by Regulation (EU) 2018/1042 on 23 July 2018.

In conclusion, the final text of this Decision has been developed by EASA and takes into consideration all comments received during all of the consultation phases detailed above.

The major milestones of this rulemaking activity are presented on the title page.

European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1539104939449&uri=CELEX:32012R0965>)

⁶ <https://www.easa.europa.eu/document-library/opinions/opinion-142016>

⁷ Commission Regulation (EU) 2018/1042 of 23 July 2018 amending Regulation (EU) No 965/2012, as regards technical requirements and administrative procedures related to introducing support programmes, psychological assessment of flight crew, as well as systematic and random testing of psychoactive substances to ensure medical fitness of flight and cabin crew members, and as regards equipping newly manufactured turbine-powered aeroplanes with a maximum certified take-off mass of 5 700 kg or less and approved to carry six to nine passengers with a terrain awareness warning system (OJ L 188, 25.7.2018, p. 3) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1539167289501&uri=CELEX:32018R1042>)

⁸ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1539104939449&uri=CELEX:32012R0965>)

⁹ After the publication of Opinion No 14/2016, mainly dealing with the implementing rules on air operations, several meetings of a dedicated NAA expert group took place between June and July 2018. The objective of these meetings was to provide EASA with advice on the development of the AMC & GM, taking into account the differences in the Regulation text in comparison with that proposed through the Opinion.

¹⁰ Written consultation of the Member States' Air Operations Technical Body (Air OPS TeB) and Flight Standards technical advisory bodies (FSTeC) from 11.7.2018 to 5.9.2018.

2. In summary — why and what

2.1. Why we need to change the AMC & GM

The tragic accident of the Germanwings Flight 9525 reminded the international aviation community that the medical and psychological conditions of flight crews, if not detected, could lead to a catastrophic outcome. Shortly after the accident, the European Commissioner for Transport, Ms Violeta BULC, requested the dedicated Task Force to examine the preliminary findings of the safety investigation led by the French BEA and make recommendations in order to prevent such a disaster from happening again, and to ensure that the overall system is improved in a proactive manner. In total, the Task Force made six recommendations in July 2015. Following the consultation of the detailed concept papers with the EASA Advisory Bodies, EASA proposed changes to IRs and AMC & GM in the Air OPS and aircrew domains. The following table provides an overview of the recommendations in the areas of Air OPS and aircrew that are subject to RMT.0700.

This Decision only addresses the changes pertaining to the Air OPS domain.

Task Force recommendation No	Air OPS	Aircrew
	Addressed in Regulation (EU) 2018/1042 and in this Decision	Addressed in Opinion No 09/2016 ¹¹ (published as the outcome of the regulatory activities of both RMT.0700 and RMT.0287)
2	Psychological assessment of flight crew by Commercial Air Transport (CAT) operators	Psychological/psychiatric assessment of applicants for Class 1 medical certificates and aero-medical examiners training
3	prevention of aircrew misuse of psychoactive substances	Psychoactive substances testing for initial Class 1 medical examination
4	N/A	Training, oversight and network of aero-medical examiners
6	Flight crew support programme	N/A

Table 1 — Overview of the recommendations in the Air OPS and aircrew domains

In more detail, this Decision addresses the following recommendations:

- Psychological assessment of airline pilots before commencing line flying (Recommendation 2);
- Psychoactive substance testing by CAT operators, including risk-based alcohol testing by Member States (Recommendation 3); and
- Implementation of a support programme (Recommendation 6).

2.2. What we want to achieve — objectives

The overall objectives of the EASA system are defined in Article 1 of the Basic Regulation. This proposal will contribute to the achievement of the overall objectives by addressing the issues outlined in Section 2.1.

The specific objectives of this Decision are to:

¹¹ Opinion No 09/2016 'Update of Part-MED (Annex IV to Commission Regulation (EU) No 1178/2011) <http://www.easa.europa.eu/document-library/opinions/opinion-092016>

- (a) achieve the level of aviation safety laid down in the Basic Regulation by ensuring that:
 - (1) reasonable measures are taken so that flight crew members are psychologically suitable for CAT operations, and thus able to exercise safely the privileges of their licences; and
 - (2) medical conditions of aircrew members misusing psychoactive substances are less likely to interfere with the safe exercise of the privileges of their licences;
- (b) develop mitigation measures for aviation safety risks arising from adverse social consequences or conditions such as loss of pilot licences; and
- (c) ensure protection of personal data.

A multilayer approach has been adopted to achieve the above objectives in an effective manner and it contains preventive, corrective and follow-up measures such as:

- (1) psychological assessment of flight crew before commencing line flying;
- (2) enabling, facilitating and ensuring access to a support programme for flight crew; and
- (3) systematic testing of psychoactive substances upon employment and with due cause.

In addition, as a complementary measure: risk-based alcohol testing of flight and cabin crew of European and third-country operators by Member States at European airports to ensure an additional safety barrier.

2.3. How we want to achieve it — overview of the proposals

The outcome of the consultation of the major items was discussed in Section 2.4. ‘What are the stakeholders’ views — outcome of the consultation’ of Opinion No 14/2016. Said Opinion, while putting emphasis on the IRs, also included a detailed assessment of the draft AMC & GM.

The major technical changes, compared to the draft AMC & GM as initially proposed in association with the draft regulatory text of Opinion No 14/2016, are described below:

- **Member State alcohol testing outside the framework of the RAMP inspection programme**

New GM to Regulation (EU) No 965/2012, to clarify that if alcohol testing of flight crew and cabin crew is carried out by other authorised officials and outside the framework of the ramp inspection programme of Subpart RAMP of Annex II, e.g. by the police, those other authorised officials do not need to comply with the requirements for qualification of inspectors of Subpart RAMP of Annex II, and that Member States should ensure that these officials are qualified for carrying out alcohol tests.
- **Risk-based alcohol testing and removal of the so-called white list**

Regulation (EU) 2018/1042 does not foresee any exemption from carrying-out of alcohol testing on flight and cabin crew who are already subject to ‘random’ testing by their airline or State of operator. For this reason, the AMC & GM on alcohol testing have been revised to incorporate alcohol testing into the risk-based RAMP programme.
- **Initial alcohol testing via breathalyser**

Initial alcohol testing should be carried out via a breathalyser, being the least invasive testing method.



— **Clarification of consequences in case of a refusal to test**

A refusal by a crew member to cooperate during an alcohol test should be regarded in the same way as a positive test. It should also be regarded as a refusal to grant access in accordance with ORO.GEN.140 in the case of an EU operator or in accordance with TCO.115 of Regulation (EU) No 452/2014 in the case of a third-country operator.

— **Conduct of alcohol test**

New GM is developed to clarify that:

- alcohol tests should be carried out, if possible, at the start of an inspection and may be carried out at any time during a RAMP inspection; and
- where a further confirmation test is carried out, it should be carried out at least 15 minutes, but not more than 30 minutes, after the completion of the initial test;

— **EU CAT operator policy to prevent misuse of psychoactive substances**

An EU CAT operator may conduct testing of psychoactive substances in the following two cases:

- (a) upon employment; and
- (b) with due cause.

— **ICAO guidance on psychoactive substance abuse**

References to ICAO guidance has been simplified.

— **New GM on meaning of personnel under the direct control of the operator**

— **AMC on psychological assessment**

The AMC has been slightly amended to take into account the scenario, where the psychological assessment is not directly performed, but overseen by a psychologist.

— **AMC on internal psychological assessment for non-complex operators**

To reflect the amendments to the respective IRs, new AMC and GM have been inserted on how to perform an internal psychological assessment for non-complex operators.

— **GM on support programme**

New GM has been developed to explain the meaning of the term ‘peer’.

2.4. How we address safety recommendations (SRs)

The following table summarises the outcome of EASA’s assessment of *the relevant safety recommendations* within the context of RMT.0700 addressed to EASA.

<p>Safety recommendation FRAN-2016-014 (BEA)</p> <p>Loss of licence</p>	<p>Safety recommendation: EASA ensure that European operators include in their Management Systems measures to mitigate socio-economic risks related to a loss of licence by one of their pilots for medical reasons.</p> <p>The co-pilot was aware of the decrease in his own medical fitness and of the potential impact of his medication. However, he did not seek any advice from an AME, nor did he inform his employer. One of the explanations lays in the financial consequences he would have faced in case of the loss of his licence.</p>
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	<p>His limited Loss of License insurance could not cover his loss of income resulting from unfitness to fly. More generally, the principle of self-declaration in case of a decrease in medical fitness is weakened when the negative consequences for a pilot of self-declaration, in terms of career, financial consequences, and loss of self-esteem, are higher than the perceived impact on safety that failing to declare would have.</p> <p>Organisations, especially airlines, can reinforce self-declaration of a decrease in medical fitness of their staff, by acting on some of the consequences of unfitness, by offering motivating alternative positions and by limiting the financial consequences of a loss of licence, for example through extending loss of licence coverage.</p> <p>References:</p> <p>FRAN-2016-14: Final Report on the accident to the Airbus A320-211 operated by Germanwings with registration D-AIPX, at Prads-Haute-Bléone (Alpes-de-Haute-Provence, France), France, on 24 March 2015, issued by the BEA (Bureau d'Enquêtes et d'Analyses pour la sécurité de l'aviation civile)</p> <p>Outcome: Regulation (EU) 2018/1042 includes a requirement for European CAT operators to provide access to a support programme. The accompanying GM to the newly introduced CAT.OP.MPA.215 follows up on the safety recommendation FRAN-2016-014 as follows:</p> <p>'GM4 CAT.GEN.MPA.215 Support programme ELEMENTS CONTRIBUTING TO A SUPPORT PROGRAMME</p> <p>When implementing a support programme, the operator should pay attention to the following:</p> <ul style="list-style-type: none"> (a) establishment and verification of operational and data protection procedures; (b) selection and training of dedicated and experienced staff and peers; (c) offer of motivating alternative positions to flight crew in case a return to in-flight duties is not possible; and (d) limitation of the financial consequences of a loss of licence, for example through extending loss of licence coverage.'
<p>Safety recommendation FRAN-2016-021 (BEA)</p>	<p>Safety recommendation: Promotion of pilot support programmes</p> <p>The investigation has shown that in spite of the onset of symptoms that could be consistent with a psychotic depressive episode and the fact that he was taking medication that made him unfit to fly, the co-pilot did not seek any aero-medical advice before exercising the privilege of his licence. This is likely the result of difficulties in overcoming the stigma that is attached to mental illness, and the prospects of losing his medical certification and therefore his job as a</p>

Support programme	<p>pilot. Self-declaration in case pilots experience a decrease in medical fitness or starting a regular course of medication can be fostered if psychological support programmes are available to crews who experience emotional or mental health issues. Existing programmes, overseen by peers, provide a ‘safe zone’ for pilots by minimising career jeopardy as well as the stigma of seeking mental health assistance. These programmes are sometimes underutilised for reasons such as: employees are questioning the confidentiality of the service; the perception that a stigma is attached to asking for professional help with personal matters; or lack of awareness of the programme and its capabilities. The management of a decrease in medical fitness can be optimised by including the intervention of peers and/or family members. The Aerospace Medical Association (AsMA) recommends extending awareness of mental health issues beyond the physician to facilitate greater recognition, reporting and discussion. Peer support systems are well implemented in major airlines, particularly in North America, where just culture principles are well known. However, these types of systems may pose significant implementation challenges when they are applied to smaller-sized organisations that are less mature and have a different cultural background. For these peer support groups to be efficient, crews and/or their families need to be reassured that mental health issues will not be stigmatised, concerns raised will be handled confidentially, and that pilots will be well supported, with the aim of allowing them to return to flying duties. The promotion of pilot support programmes has already been recommended by AsMA Expert WG, UK DfT/CAA WG, BMVI WG, and the EASA Task Force.</p>
	<p>References:</p> <p>FRAN-2016-21: Final Report on the accident to the Airbus A320-211 operated by Germanwings with registration D-AIPX, at Prads-Haute-Bléone (Alpes-de-Haute-Provence, France), France, on 24 March 2015, issued by the BEA (Bureau d’Enquêtes et d’Analyses pour la sécurité de l’aviation civile)</p>
	<p>Outcome: Regulation (EU) 2018/1042 includes a new requirement for European CAT operators to provide access to a support programme in the new CAT.GEN.MPA.215. Several accompanying AMC and GM establish in detail the functioning of a successful support programme with a clear emphasis on the importance of confidentiality.</p> <p><i>During the course of 2017 and 2018, EASA has supported multi-stakeholder initiatives (see www.eppsi.eu) to promote best practices on setting up a support programme and to prepare EU CAT operators for this new IR. In addition, GM clarifies that nothing should prevent the operator from extending the scope of the support programme to include, apart from flight crew, other safety-sensitive personnel, e.g. cabin crew or maintenance staff, as well.</i></p>

3. References

3.1. Related regulations

- Commission Regulation (EU) 2018/1042 of 23 July 2018 amending Regulation (EU) No 965/2012, as regards technical requirements and administrative procedures related to introducing support programmes, psychological assessment of flight crew, as well as systematic and random testing of psychoactive substances to ensure medical fitness of flight and cabin crew members, and as regards equipping newly manufactured turbine-powered aeroplanes with a maximum certified take-off mass of 5 700 kg or less and approved to carry six to nine passengers with a terrain awareness warning system (OJ L 188, 25.7.2018, p. 3)
- Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1)

3.2. Affected decisions

- Decision 2014/019/R of the Executive Director of the Agency of 24 April 2014 adopting Guidance Material to Regulation (EU) No 965/2012 – ‘GM to Regulation (EU) No 965/2012’
- Decision 2014/025/R of the Executive Director of the Agency of 28 July 2014 adopting Acceptable Means of Compliance and Guidance Material to Part-ARO of Commission Regulation (EU) No 965/2012 and repealing Decision 2014/014/R of the Executive Director of the Agency of 24 April 2014 — ‘AMC and GM to Part-ARO — Issue 3’
- Decision 2014/015/R of the Executive Director of the Agency of 24 April 2014 adopting Acceptable Means of Compliance and Guidance Material to Part-CAT of Commission Regulation (EU) No 965/2012 and repealing Decision 2012/018/R of the Executive Director of the Agency of 24 October 2012 — ‘AMC and GM to Part-CAT — Issue 2’

All Decisions are available at <http://easa.europa.eu/agency-measures/agency-decisions.php>.

