



# Opinion No 14/2016

## Aircrew medical fitness

### Implementation of the recommendations made by the EASA-led *Germanwings Task Force* on the accident of the Germanwings Flight 9525 (Changes to Regulation (EU) No 965/2012)

RMT.0700

#### EXECUTIVE SUMMARY

This Opinion addresses the safety issues identified by the EASA-led Germanwings Task Force (hereinafter referred to as the 'Task Force') on the accident of the Germanwings Flight 9525.

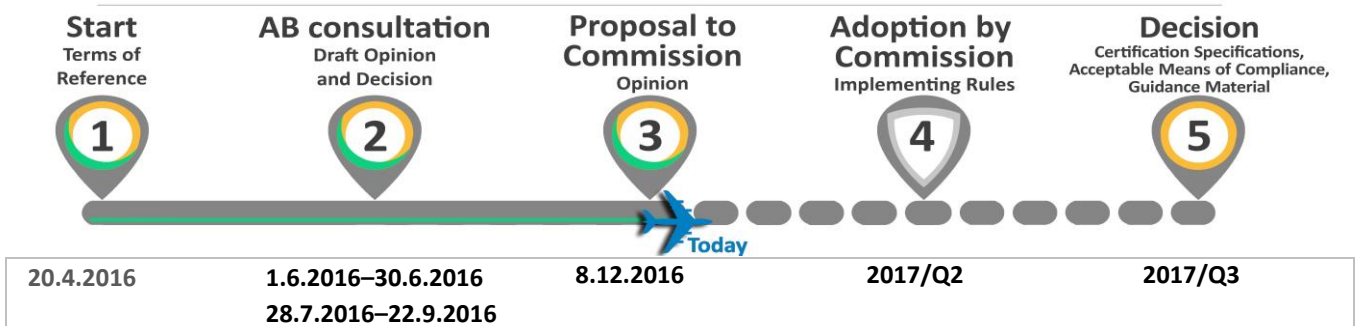
Following the publication of the French Bureau d'Enquêtes et d'Analyses pour la Sécurité de l'Aviation Civile (BEA) preliminary investigation report on 6 May 2015, the Task Force examined the findings of the BEA report and assessed the adequacy of the European air safety and security rules. As a result of this work, 6 recommendations were addressed to the European Commission on 16 July 2015 related to the aircrew rules (Regulation (EU) No 1178/2011), as well as the air operations (Air OPS) rules (Regulation (EU) No 965/2012). This Opinion only proposes changes to the Air OPS implementing rules (IRs), which can be summarised as follows:

- (a) Preventive measures such as:
  - (1) carrying out a psychological assessment of the flight crew before commencing line flying;
  - (2) enabling, facilitating and ensuring access to a flight crew support programme; and
  - (3) performing systematic drug and alcohol (D&A) testing of flight and cabin crew upon employment.
- (b) Corrective and follow-up measures such as performing flight and cabin crew D&A testing:
  - (1) after a serious incident;
  - (2) after an accident;
  - (3) following a reasonable suspicion; and
  - (4) unannounced after rehabilitation and return to work.
- (c) A complementary measure: mandatory random alcohol screening of flight and cabin crew within the ramp inspection programme to ensure an additional safety barrier.

This last measure mandates random alcohol screening of flight and cabin crew members who are not already subject to a psychoactive substance testing programme under a national scheme. EASA will provide the Member States with a list of operators whose crew members will not be subject to random alcohol screening during ramp inspections to avoid double testing.

<b>Action area:</b>	Safety, aviation personnel		
<b>Affected rules:</b>	Air OPS Regulation (Cover Regulation, Annex I (Definitions for terms used in Annexes II to VIII), Annex II (Part-ARO), and Annex IV (Part-CAT))		
<b>Affected stakeholders:</b>	Member States, CAT operators, flight and cabin crew		
<b>Driver:</b>	Safety	<b>Rulemaking group:</b>	No
<b>Impact assessment:</b>	Full	<b>Rulemaking Procedure:</b>	Special (Article 15 'Direct publication')

• EASA special rulemaking procedure milestones



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## 1. About this Opinion

### 1.1. How this Opinion was developed

The European Aviation Safety Agency (EASA) developed this Opinion in line with Regulation (EC) No 216/2008<sup>1</sup> (hereinafter referred to as the 'Basic Regulation') and the Rulemaking Procedure<sup>2</sup> described in the Management Board Decision No 18-2015. Specifically, the draft IRs proposed through this Opinion, as well as the associated acceptable means of compliance (AMC) and guidance material (GM), have been consulted with the EASA Advisory Bodies in accordance with Article 15 'Special rulemaking procedure: direct publication' of said MB Decision.

The scope and timescales for the task were defined in the related Terms of Reference (ToR)<sup>3</sup>. The ToR for RMT.0700 are 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.

123 valuable comments were received by the Advisory Bodies on the concept papers, providing thus EASA with a better understanding of what the regulatory proposal should include. Additional comments on how to address the safety issues raised by the Task Force recommendations were received in March 2016 as a result of the consultation of the ToR for RMT.0700.

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 most of the proposals which are included in this Opinion.

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. This consultation did not include any regulatory proposal on random D&A testing. At the Conference, an impact assessment on the subject was presented for discussions.

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<sup>1</sup> Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1) (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1464170711619&uri=CELEX:32008R0216>).

<sup>2</sup> The Agency is bound to follow a structured rulemaking process as required by Article 52(1) of Regulation (EC) No 216/2008. Such a process has been adopted by the Agency's 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 the Agency for the issuing of opinions, certification specifications and guidance material (<http://www.easa.europa.eu/system/files/dfu/EASA%20MB%20Decision%2018-2015%20on%20Rulemaking%20Procedure.pdf>).

<sup>3</sup> <http://www.easa.europa.eu/system/files/dfu/ToR%20RMT.0700%20Issue%201.pdf>



The Conference, attended by more than 130 participants, provided valuable input. In addition, written feedback from 10 NAAs, 2 airlines, as well as 4 European industry and flight crew associations and 1 medical association was received during the Advisory Bodies' consultation on the changes proposed in June to the Air OPS rules.

Following consideration of the feedback received in June by the Advisory Bodies and at the Conference, an additional consultation of the proposed changes to the Air OPS rules, including a proposal to implement random D&A testing, was carried out from 28 July to 22 September 2016.

As the comments on the topic of random D&A testing received during the consultation ended on 22 September 2016 were quite heterogeneous, an additional technical meeting with the commentators took place on 3 November 2016. This Opinion reflects also the outcome of the discussion held at that meeting.

In conclusion, the final text of this Opinion and the draft regulation have been developed by EASA having taken into consideration all comments received in the consultation phases detailed above. The draft rule text proposed by EASA is published on the EASA website<sup>4</sup>.

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

## 1.2. The next steps

This Opinion contains the proposed amendments to Regulation (EU) No 965/2012<sup>5</sup> (hereinafter referred to as the 'Air OPS Regulation') and their potential impacts. It is submitted to the European Commission to be used as a technical basis in order to prepare an EU regulation.

For information, EASA published the draft text for the related EASA decision containing AMC/GM. The final decision issuing the AMC/GM will be published by EASA when the European Commission has adopted the regulation.

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<sup>4</sup> <http://easa.europa.eu/document-library/opinions>

<sup>5</sup> 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) (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:296:0001:0148:EN:PDF>).



## 2. In summary — why and what

### 2.1. Why we need to change the rules — issue/rationale

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, can 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.

6 recommendations (see the Annex to this document) were made by the Task Force in July 2015. Following the consultation of the detailed concept papers with the EASA Advisory Bodies, EASA believes that 4 of these recommendations, namely recommendations 2, 3, 4, and 6, require regulatory changes 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 Opinion only addresses the changes pertaining to the Air OPS domain.

Task Force recommendation No	Air OPS	Aircrew
	Addressed in this Opinion	Addressed in Opinion No 09/2016 <sup>6</sup> (published as the outcome of the regulatory activities of both RMT.0700 and RMT.0287)
2	Psychological assessment of flight crew by CAT operators	Psychological/psychiatric assessment of applicants for Class 1 medical certificates and aero-medical examiners training
3	CAT operators' 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 Opinion addresses the following recommendations:

- Psychological assessment of airline pilots before entering service (Recommendation 2);
- Mandating D&A testing: random, post-incident/accident, with due cause (Recommendation 3); and
- Implementation of pilot support and reporting systems (Recommendation 6).

Concerning Recommendation 3, testing is proposed in the following cases: when employed by the CAT operator; post-incident, post-accident, with due cause, as part of a follow-up, after a positive test result, and randomly. Specifically, with regard to the random testing this Opinion proposes:

1. Alcohol screening of flight and cabin crew within the ramp inspection programme;

<sup>6</sup> 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>



2. Unannounced D&A testing as follow-up of rehabilitation and return to work.

## 2.2. What we want to achieve — objectives

The overall objectives of the EASA system are defined in Article 2 of the Basic Regulation. This proposal will contribute to the achievement of the overall objectives by addressing the issues outlined above.

The specific objectives of this regulatory proposal are to:

- (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 multi-layer approach has been adopted to achieve the above objectives in an effective manner. It is articulated as follows:

- (a) Preventive measures such as:
  - (1) carrying out a psychological assessment of the flight crew before commencing line flying;
  - (2) enabling, facilitating and ensuring access to a flight crew support programme; and
  - (3) performing systematic D&A testing of flight and cabin crew upon employment.
- (b) Corrective and follow-up measures such as performing flight and cabin crew D&A testing:
  - (4) after a serious incident;
  - (5) after an accident;
  - (6) following a reasonable suspicion; and
  - (7) unannounced after rehabilitation and return to work.

The above measures do not prevent any CAT operators from establishing a random D&A testing programme as additional preventive measure.

- (c) A complementary measure: mandatory random alcohol screening of flight and cabin crew within the ramp inspection programme to ensure an additional safety barrier.

This last measure mandates random alcohol screening of flight and cabin crew members who are not already subject to a psychoactive substance testing programme under a national scheme. EASA will provide the Member States with a list of operators whose crew members will not be subject to random alcohol screening during ramp inspections to avoid double testing.



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

EASA proposes to amend:

- the Air OPS Regulation (Cover Regulation);
- Annex I (Definitions) to the Air OPS Regulation;
- Annex II (Part-ARO) to the Air OPS Regulation
- Annex IV (Part-CAT) to the Air OPS Regulation;
- AMC/GM to Part-ARO to the Air OPS Regulation;
- AMC/GM to Part-CAT to the Air OPS Regulation;

An overview of the main proposed changes follows:

- For random alcohol testing (recommendation 3), a new article in the Cover Regulation stipulates that Member States shall ensure alcohol testing of flight and cabin crew members in accordance with national legislation. Alcohol testing shall be conducted under the ramp inspection programme by ramp inspectors or by officials authorised thereto. However, Member States may conduct alcohol testing of flight and cabin crew members in accordance with national testing programmes. The IR stipulates mandatory random alcohol screening of flight and cabin crew within the ramp inspection programme for those crew members who are not already subject to a psychoactive substance testing programme under a national scheme. EASA will provide the Member States with a list of operators whose crew members will not be subject to random alcohol screening during ramp inspections to avoid double testing. The AMC/GM provide details on establishing the list of said operators and on the conduct of alcohol testing.
- Three new definitions on ‘misuse of substances’, ‘psychoactive substances’ and ‘safety-sensitive personnel’ in Annex I to the Air OPS Regulation.
- For pilots’ psychological assessment by operators (recommendation 2), a new IR stipulates that a flight crew should have undergone a psychological assessment before commencing line flying. For certain small operators, the psychological assessment can be replaced with an internal assessment. The AMC/GM provide details on the content and quality of the assessment, who is allowed to conduct such an assessment, and how operators can implement this assessment.
- For the prevention of problematic use of psychoactive substances (recommendation 3), new IRs along with the associated AMC/GM are proposed to mitigate the risks related to the misuse of psychoactive substances. The proposed IRs require operators to establish the necessary policy and procedures. The proposed AMC specifies that flight crew and cabin crew should be tested for psychoactive substances upon employment by the operator; after a serious incident/accident, with due cause, and as part of a follow-up after rehabilitation and return to work. GM is proposed including reference to existing guidance material, e.g. ICAO Doc 9654, as well as reference to experience gained with peer support and reporting systems and their ability to adequately mitigate, in a proportionate manner, the related safety risk.
- For the support programme for flight crew (recommendation 6), a new IR and AMC/GM to the Air OPS Regulation are proposed to ensure that all flight crew have access to a support programme. Such a support programme must enable self-declaration in case of a decrease in





medical fitness and, if appropriate, allow the crew member to receive temporary relief from flight duties and be referred to professional advice. In order to effectively and efficiently foster self-declaration, the support programme should ensure that risks related to fear of loss of licence are properly mitigated. Apart from the proposed new IR, EASA proposes AMC and GM to enable operators and NAAs to start implementing the recommendations in a proactive manner, including best practices. The AMC and GM state the enablers of an effective support programme, such as:

- protection of personal data;
- essential trust between management and crew being the foundation of a successful support programme;
- an effective safety culture; and
- support in case of loss of licence.

## 2.4. What are the stakeholders' views — outcome of the consultation

### 2.4.1. General comments received

- (a) Several commentators stated that some of the requirements placed at the consultation stage at IR level could rather be included in AMC/GM. Other commentators stated that what is proposed seems to be disproportionate (or unachievable) for small operators (non-complex operators). Another commentator stated that the requirements should at least be alleviated or that they should even not apply to small operators, when applicable on 21 April 2017.

*EASA carefully assessed the feedback from stakeholders regarding proposed changes to IRs vs AMC/GM. EASA considers that, for what concerns providing access to a pilot support programme, the requirements should be mandatory, thus an IR is necessary.*

*However, the feedback obtained from stakeholders during the consultation resulted in some changes to introduce more flexibility for operators, e.g. by ensuring that operators can make use of third-party providers of support programmes, rather than having to establish their own support programme from scratch. Additional flexibility for non-complex operators has been introduced following the last consultation activities: for operators with a stable and small workforce of pilots, the psychological assessment can be replaced with an internal assessment.*

- (b) One commentator stated that the RIA does not justify the inclusion of cabin crew and other safety-sensitive personnel.

*EASA would like to stress that this Opinion is consistent with the Standardised European Rules of the Air (SERA)<sup>7</sup>. As for the reasons to include cabin crew, they have been addressed in the RIA.*

### 2.4.2. New definitions in Annex I (Definitions) to the Air OPS Regulation

- (a) One commentator stated that the term 'misuse of substances' should be replaced with 'problematic use of psychoactive substances' in line with the ICAO Manual on Prevention of

<sup>7</sup> SERA.2020, transposing ICAO Annex 2, paragraph 2.5, into Commission Regulation (EU) No 923/2012 of 26 September 2012 to address the risks associated with the problematic use of psychoactive substances by safety-sensitive personnel.



Problematic Use of Substances in the Aviation Workplace<sup>8</sup> (hereinafter referred to as the 'ICAO Manual').

*The proposed wording is aligned both with the wording proposed in Opinion No 09/2016, amending Part-MED of the Aircrew Regulation, and that in Commission Regulation (EU) 2015/340<sup>9</sup>.*

- (b) One commentator stated that in the definition of psychoactive substances, the word 'coffee' should be replaced by 'caffeine'.

*EASA agrees and has revised the definition accordingly. The definition is also aligned with the definition in Part-MED as proposed with Opinion 09/2016.*

- (c) One commentator stated that the EASA proposal should take into account that the ICAO Manual might be outdated since it was issued in 1995.

*EASA consulted with ICAO on the manual and ICAO presented the manual at the workshop organised by EASA in December 2015. The manual is still encompassing all the key elements. EASA will cooperate with ICAO to work on a revision of the manual.*

- (d) Some commentators stated that the definition of psychoactive substances is very broad and is introduced into the AMC without proper consideration of how practical it is for operators to take test samples for the specific substances in a standard line operation. An additional definition should be added for the subset of substances which are suitable for sampling for testing in a line operation.

*EASA requested input from operators on their respective random D&A testing policy. Only very few operators responded. The feedback obtained confirmed that the regulatory proposal should not contain a definitive list of substances and respective cut-off limits. Therefore, the EASA proposal is aligned with the ICAO Manual, which states that the testing policy should be adapted to the local circumstances and national/regional prevalence of drug and alcohol misuse.*

### 2.4.3. Alcohol testing during ramp inspections

- (a) Many commentators questioned the effectiveness of alcohol testing during ramp inspections. Some commentators stated that ramp alcohol testing will negatively impact on flight safety, because false positive alcohol tests will cause a lot of stress to the pilot and will delay the flight whilst a second test is carried out. The question on a pilot's fitness to fly following a negative second test, high levels of stress being present in such a process, is not adequately assessed. This poses a significant risk for flight safety during a period when the pilot focus should exclusively be on the safe operation of the flight. Those commentators also argued that the economic negative impact for the operator is higher than estimated in the RIA. Furthermore, the economic impact of brand and reputational damage from a pilot being escorted from a flight after a false positive may be in the order of millions of euros. Said commentators also stated that random testing has

<sup>8</sup> Doc 9654 (AN/945, First Edition, 1995)

<sup>9</sup> Commission Regulation (EU) 2015/340 of 20 February 2015 laying down technical requirements and administrative procedures relating to air traffic controllers' licences and certificates pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 923/2012 and repealing Commission Regulation (EU) No 805/2011 (OJ L 63, 6.3.2015, p. 1) (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1468315553275&uri=CELEX:32015R0340>).



a very low success rate in detecting long-term issues, and data on the efficacy of short-term detection is quite heterogeneous. As such, the current proposal is not proportionate or best practice. EASA should therefore consider the issues above and mandate a requirement for a testing regime away from the flight deck, possibly prior to a duty or in other operator environments.

*EASA maintains the proposal and clarifies that the likelihood of false positive tests for alcohol screenings is very low as compared to a much higher rate for drug testing. Also, for this reason, EASA is excluding drug testing during ramp inspections. Alcohol testing via a non-invasive testing method, e.g. via a breath analyser, is very quick (12 mins). The existing ramp inspection programme has benefited aviation safety since its existence and includes many safeguards to ensure that those inspections take place out of the passengers' sight and the risk of operational delays is reduced to the minimum.*

*Finally, concerning the risk that ramp alcohol screening would negatively affect aviation safety as a result of the stress that crew members would be exposed to, and the subsequent decrease of their ability to perform their duties safely, EASA is not aware of any scientific evidence of such impact on individuals. Alcohol testing on a random basis is already performed on aircrew members in many Member States by the police and in some cases by operators. In addition, random testing is common for many transportation workers, e.g. car, truck and train drivers.. There is no scientific evidence, known to EASA, that such testing has negatively affected the safety of the related transport modes.*

- (b) Many commentators stated that there is a contradiction between the proposed IR, stating that alcohol testing shall be based on a risk assessment, and the associated AMC, including the possibility to randomly test a flight crew member. If the testing is based on a risk assessment, then stakeholders requested AMC or GM to describe the associated criteria.

*EASA has considered the comments and has revised its proposal. The new ARO.RAMP.106 clarifies that EASA shall provide a prioritisation list based on a risk assessment only for those European and third-country operators, who are not already subject to alcohol testing as part of a national alcohol testing programme. Unless there is reasonable cause or suspicion, crew members from operators who are already subject to a national testing programme shall not be randomly tested under the ramp inspection programme.*

- (c) One commentator requested to delete the term 'random' from the proposed AMC text on ramp inspections including alcohol testing, since the proposed IRs refer to a risk assessment rather than pure random testing.

*EASA agrees and has removed the term 'random' from the proposed text.*

- (d) Regarding the alcohol testing equipment, one commentator stated that the testing must be done via a breathalyser screening device and that this should be specified, to avoid possible utilisation of other types of tests. Standardisation at European level should be ensured to provide a level playing field. Experience from established testing programmes, like the Federal Aviation Administration (FAA) one, could be used as guidance. Standards should be provided on the place where testing will be done with consideration to ensure privacy.



*EASA relies on the well-established ramp inspection programme to disseminate to NAAs information about screening equipment. The proposal foresees that testing should be non-invasive. The IR does not prescribe a testing method, in order to allow for technological innovation. A newer equipment other than a breathalyser might be more advantageous, e.g. quicker, less invasive, more tamper-proof, etc. For this reason, the EASA proposal does not prescribe the equipment or the technology to be used.*

- (e) Many commentators stated that alcohol testing during ramp inspections conducted on a random basis is still impossible in many Member States due to absence of rules authorising it. As a consequence, the implementation of random alcohol testing will require to change the national law and this will take time.

*EASA agrees that it will take time to adapt the national legal environment. For this reason, the revised proposal foresees a transition period of 24 months.*

- (f) One commentator stated that immediate communication with the operator must be ensured.

*EASA maintains its proposal, since the existing RAMP IR, AMC and GM already include provisions on communication with the operator.*

- (g) One commentator stated that the reliability of the testing method applied during the ramp inspections, as well as the low false positive results should be assured.

*EASA maintains its proposal, since AMC1 ARO.RAMP.106(a) specifies that the testing methodology should apply recognised quality standards.*

- (h) Regarding including data on alcohol tests into the ramp database, one commentator stated that the names of the affected pilots should not be published; instead, the data should include flight identification information, in compliance with Appendix IV to Part ARO of the Air OPS Regulation. Another commentator stated that whenever the police conducts such tests, according to national law, all criminal investigation must be kept secret. Only members of the Police and the prosecutor concerned, as well as the interested party, have the right to know details of the investigation.

*EASA agrees with the comment that the name should not be included into the database. This is already a standard practice today within the ramp inspection programme. EASA has amended the proposed IR (ARO.RAMP.106(e)) accordingly.*

- (i) One commentator stated that the alcohol levels mentioned in the AMC to the proposed IR on alcohol testing should be transferred to the IR. A transfer to the IR is necessary, to avoid that positive tests can be contested. Otherwise, court decisions might not warrant a sanction, even more so a penal sanction. Moving the maximum threshold into the IR would also guarantee a unified implementation of this requirement, while allowing Member States to enforce more restrictive levels if they wish so.

*EASA does not consider that the Air OPS Regulation is the appropriate legal basis for criminal proceedings*

- (j) One commentator stated that the AMC related to testing, which refers to the use of recognised quality standards applied to the testing methodology, should only apply in cases where the



inspector's privileges have been extended to also include alcohol testing during ramp inspections.

*It is reminded that the EASA proposal only applies whenever Member States conduct alcohol testing within the ramp inspection programme.*

- (k) One commentator questioned the use of the term 'BAT' in proposed GM to the IR on alcohol testing. BAT refers to the qualification of a 'breath alcohol technician (BAT)'. The commentator stated that this is a US government official qualification title. Therefore, the commentator proposed to replace the text of GM to read 'The inspector [...] should be qualified to perform breath alcohol testing.' Another commentator stated that to ensure testing is done professionally and produces reliable samples, it is important to specify that only trained testers carry out these tests. Yet, another commentator stated that the requirement for the inspectors to be qualified should be moved to the IRs and not be at GM level.

*EASA agrees and has changed the GM accordingly. The term 'BAT' has been replaced with the wording proposed by the commentator and has been moved to AMC. In addition, EASA agrees that ramp inspectors performing alcohol tests should be trained and has amended the respective AMC accordingly to include such a provision.*

- (l) One commentator stated that the term 'crew members' would open the way for testing also to cabin crew. While this may not be the EASA intention, it would definitely be logical and consistent to test all types of safety-sensitive personnel on board an aircraft. This needs to be evaluated and clarified in this provision, as well as other provisions where the more specific term 'flight crew' is used.

*EASA has amended the proposed rule text. Alcohol screening within the ramp inspection programme and D&A testing in specific cases are applicable to both flight and cabin crew members.*

- (m) One commentator stated that if EASA is proposing that random alcohol testing during ramp inspections shall include cabin crew, the requirement should also ensure that cabin crew have access to a support programme.

*The current regulatory proposal does not explicitly require cabin crew to be included in support programme, but the proposal does not prevent any support programme from providing support to cabin crew, or any other aviation safety-sensitive personnel, as well.*

*As it will take time for the support programmes to reach the necessary maturity level across the Member States, EASA has adopted a stepped approach to phase-in the implementation of such support programmes and has thus not included in the revised Opinion a requirement to provide for cabin crew access to support programmes. Furthermore, the stepped approach adopted by EASA is consistent with the existing distinction established between the requirements for aero-medical fitness of flight crew and cabin crew. The first step proposed by EASA addresses issues mainly related to Class 1 aero-medical certification.*

- (n) One commentator stated that alcohol tests should be performed by the police and not the inspector. Making ramp inspectors responsible for those tests would create undue administrative burden for the competent authority, and would require organisational and national legislative changes. During the random checks at the crew centre, all departing crew



members are checked. The commentator was not in favour of alcohol tests during ramp checks. The experience is that the involvement of law enforcement bodies during ramp checks can negatively influence the position of the inspector. In addition, the tests should not be done at the ramp, but this must be done preferably in crew centres or at least out of sight of the passengers and the general public. The responsibility for the alcohol checks must remain with the respective law enforcement officers. The way of exchange of information and responsibilities can be mutually agreed with the competent authority for aviation and the national law enforcement bodies, i.e. the aviation police. In the current situation, the inspector is already in close contact with the police. It will also be difficult to share the results of the police inspection with the ramp database.

*The EASA proposal foresees the possibility for alcohol testing to be conducted also by national law enforcement officers under a national system. In this case, the data of the tests should be included into the ramp database.*

- (o) Many commentators (both industry and NAAs) raised concerns that the testing should not take place inside the cockpit and flight crew members must be screened away from passengers, as well as from other non-flight crew personnel. Doing otherwise would risk to undermine the passengers' confidence in the safe operation of their flight and in the professionalism of the flight crew. In addition, one commentator stated that testing should never take place during cleaning or refuelling or catering, where other staff are present in the aircraft cabin. In addition, some stakeholders requested that it should be specified that no delays should be associated with the testing in normal conditions, meaning when no positive results are detected.

*Existing provisions in AMC/GM applicable to all ramp inspection checks already include clear instructions for ramp inspectors to avoid any conflict with passengers or other staff and to avoid delays due to ramp checks. Inspectors are already trained in this regard. The EASA proposal does not determine that the test must take place in the cockpit. Where deemed possible, the test can also be performed at another location. Since ramp inspections are a well-coordinated European programme with frequent feedback loops from NAAs and stakeholders, any separate issues due to alcohol testing can be easily addressed via work instructions or additional guidance material. However, EASA understands the concerns raised and has amended the related GM specifying that alcohol tests should preferably be conducted before duty commences outside the cockpit, e.g. in a crew centre.*

#### **2.4.4. Operators' policy and procedures on the prevention of misuse of psychoactive substances**

- (a) One commentator commented that point (e) of AMC1 CAT.GEN.MPA.170(c) states that the operator has to define which psychoactive substances have to be tested. The commentator requested an epidemiological study to be conducted to define which substances have to be tested for. This study could be carried out by several European aero-medical centres (AeMCs) randomly chosen, on a given day, using questionnaires and biochemical tests for different psychoactive substances on crew members during medical examinations (e.g. cannabis, ecstasy, cocaine, most prescribed benzodiazepine-type anxiolytics). Depending on the results, choices of substances to be systematically tested for could be established by an EASA scientific committee. In addition, the lack of cut-off levels associated with psychoactive substances impairs a consistent application of these requirements. An indication of the levels in the text would be appreciated.



*This comment was addressed separately in a technical meeting<sup>10</sup> on the EASA proposed amendment to Part-MED of Regulation (EU) No 1178/2011 (hereinafter referred to as the Aircrew Regulation)<sup>11</sup>.*

*According to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the speed of innovation of new synthetic drugs is increasing over the last years. Consequently, as regards the Air OPS Regulation, EASA maintains its proposal that the operators are best placed to define the substances to be tested, and adapt their policy to the actual threats and prevalence of new drugs, including synthetic drugs that flight crews are exposed to.*

- (b) One commentator requested to replace the term ‘detection’ with the term ‘prevention’ when referring to an objective, transparent and non-discriminatory procedure in cases of misuse of psychoactive substances by flight and cabin crew and other safety-sensitive personnel.

*Since the comment is in line with the ICAO manual, EASA agrees and has amended the proposed IR.*

- (c) Some commentators requested to extend the scope of the operator’s D&A testing policy and procedures from flight crew and cabin crew to cover also other safety-sensitive personnel. Other commentators disagreed and stated that the Air OPS rules only refer to flight and cabin crew. In addition, there has been no consultation with other groups of staff on the proposal and some staff members, e.g. ground handling staff are outside of the EASA remit. Therefore, the commentators requested to delete the references to testing for staff other than flight and cabin crew.

*EASA maintains its proposal to refer also to other safety-sensitive personnel, next to flight and cabin crew. While it is correct that the Air OPS rules do not apply to ground handling staff or operational control staff, the Air OPS rules are directed towards the operator; in this case, the CAT operator. In addition, this Opinion is consistent with SERA as previously mentioned in Section 2.4.1.*

- (d) One commentator requested to provide a definition of other safety-sensitive personnel.

*A definition of ‘safety-sensitive personnel’ has been included in the IR (Annex I to the Air OPS Regulation).*

- (e) One commentator stated that the term ‘with due cause’ should be better explained.

*EASA has amended its proposal. The new AMC (AMC2 CAT.GEN.MPA.170(b)) states that the operator’s policy should ensure testing for psychoactive substances in the case of due cause, e.g. following reasonable suspicion based on an assessment of appropriately trained personnel. Listing all possibilities of a reasonable suspicion in AMC or GM is not possible.*

- (f) One commentator stated that the term ‘post-serious incident’ should be better explained to know when D&A testing should be performed.

<sup>10</sup> Member States Advisory Body (MAB) meeting of 22 November 2016

<sup>11</sup> Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p. 1) (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1480346438177&uri=CELEX:32011R1178>).



*EASA agrees and has amended the regulatory proposal that now explains that it refers to a serious incident within the meaning of Regulation (EU) No 996/2010 unless the causes of the event are free from any human factor contributor.*

- (g) Another commentator stated that personnel should be offered every opportunity to get help, and to be freed from their schedule, to allow them to recover and continue their careers. This is non-punitive. If, however, they report for duty drunk or unfit to fly due to being under the influence of drugs, then the distinction between a non-punitive and a just-culture should take effect. If personnel knowingly endanger flight safety, that should remain a legitimate reason to end their employment. Furthermore, if getting caught just means that you will be forced to join a support programme, then that reduces the incentive to actively seek for help for one's problem. The provision to report not-fit-to-fly is a vital safety barrier. This barrier must be maintained. Therefore, point (g) of the proposed AMC should read 'the process to be followed in case of a confirmed positive test result.' and should NOT refer to a support programme. In this case, the process should consider the impact on the individual, e.g. confidentiality, employment, and loss of licence.

*EASA maintains its proposal to include reference to the support programme in the AMC.*

- (h) One commentator stated that the internal non-punitive appeal process should be maintained in the AMC as proposed and argued that EASA should set a generic requirement that the appeal process should be 'non-punitive'. This is because in some companies the safety/management culture is such that an appeals process could be used by management in a punitive manner. This would discourage crew members from appealing. For most companies with a solid safety and just culture, such a 'non-punitive' requirement should be no problem to comply with, but for some it would be necessary to set this requirement.

*EASA maintains its proposal to refer to the appeal process. Just culture is an underlying concept in aviation safety and applies not only to the appeal process. Therefore, a separate reference to non-punitive appeal process is not deemed necessary.*

- (i) Stakeholders requested that direct references to support programmes in the proposed rule on prevention of misuse of psychoactive substances be deleted as the scope of the support programmes is expected to be wider (e.g. to cover for mental health and psychological issues, provide critical incidents support, and ensure well-being).

*EASA agrees and has introduced a separate IR related to the prevention of misuse of psychoactive substances.*

- (j) Some stakeholders requested to include, in case of a confirmed positive test result, a requirement to ensure that the medical assessor of the licensing authority is informed. Other commentators stated that what is meant by 'clearly defined cases (e.g. medical or safety issues)' is unclear, de facto leaving room for interpretation. Given the significant consequences of such a reporting to the authority, it was requested that EASA specify in which cases and/or under which circumstances the medical authority of the licensing authority should be informed, by stating 'and where there is a clearly evident and imminent risk to public safety'. Making the link to the support programme, commentators also stated that the support programme should have a team of pilots, a psychologist, and an aero-medical expert to ensure that each case is reported to the authority, where public safety is significantly and imminently endangered. In such a case, the





doctor should first consult the other members of the team to verify the significance, severity and imminence of the threat to safety. If the conclusion is affirmative, then the case will have to be reported to an aero-medical examiner (AME) or the medical assessor of the licensing authority that should consider the willingness to seek treatment.

*EASA agrees and has introduced in the proposed IR a requirement that the operator must inform the medical assessor of the licensing authority in case of a confirmed positive test result. In addition, EASA maintains the proposed GM referring to the aircrew member's obligation to seek aero-medical advice in case of a decrease in medical fitness in accordance with MED.A.020 of the Aircrew Regulation.*

- (k) One commentator stated that a basic catalogue of testing methods, substances and cut-off criteria should be harmonised within Europe, and this decision should not be left to the operator. Although some kind of substances (Annex I (Definitions) to the Air OPS Regulation (98a)) that have to be tested mandatorily are mentioned, the draft regulatory proposal misses more detailed information pertaining for instance to the methods of testing and the scheduled intervals. Therefore, the commentator suggested that the criteria for operator testing should be harmonised within the EASA Member States or at least within each Member State, so it should not be the operator's task to define which substances have to be tested. The commentator stated that as there are different points of view at national level on what exactly is considered as misuse/abuse of substances, adding that a reasonable level of standardisation based on a minimal list of known psychoactive substances — that all Member States should be able to agree upon as influencing aviation performance — is essential.

*The EASA proposal does not establish testing thresholds (cut-off limits) or testing methods. The limits for alcohol abuse are already contained in a dedicated AMC to Part-CAT. The EASA approach is in line with the ICAO Manual which recommends that testing policies should be adapted to the different local environments. The EASA proposal is also consistent with the latest conclusions reached by the EMCDDA in its European Drug Report 2016<sup>12</sup>, highlighting the importance of the regional patterns in stimulant use and harms, the different responses to drug supply and possession adopted by the Member States, and the different legal approaches in the Member States. EASA expects EU operators to develop and implement their policy on the prevention and detection of the misuse of psychoactive substances consistently with the various regional prevalence patterns alongside the different regional strategies and legal approaches adopted by the Member States. At European level, EMCDDA is the decentralised agency providing the EU and its Member States with a factual overview of European drug problems and a solid evidence base to support the drugs debate. It offers policymakers the data they need for drawing up informed drug laws and strategies. It also helps professionals and practitioners working in the field pinpoint best practice and new areas of research.*

- (l) Whereas most stakeholders stated that pure random testing is not efficient, three stakeholders were in favour of pure random testing stating that it should be included even in low prevalence populations, such as air crew, since it has been shown that random testing modifies behaviour and deters psychoactive substance misuse.

<sup>12</sup> 'European Drug Report 2016: Trends and Developments' available in various languages under <http://www.emcdda.europa.eu/publications/edr/trends-developments/2016>



*Following the outcome of the RIA, EASA proposes a multi-layer approach for addressing the safety risks related to psychoactive substance misuse. See Section 2.2.*

- (m) Some commentators stated that employee testing requirements are in conflict with national regulations (in many countries, intrusive test may only be carried out by an officer of the judicial police control).

*EASA is aware of the different legal systems in place and therefore refers to the applicable national legislation on testing of individuals in the proposed IR.*

- (n) Commentators stated that in order to enhance credibility, the persons/bodies responsible for testing must be independent, and that this should be specifically spelled out. 'E.g.' (= for example) should be changed into 'i.e.' (= this means]. Another commentator stated that the proposal is too prescriptive. It is sufficient to say that an accredited testing organisation should be used. If the policy is too specific, it creates opportunities for avoidance.

- (o) *The EASA proposal does not specify detailed cut-off levels for psychoactive substances. AMC1 CAT.GEN.MPA.170(c) on psychoactive substances establishes that testing should be objective, transparent and non-discriminatory, ensuring confidentiality and protection of data. Regarding the testing process, the AMC proposes the use of recognised quality standards, established by a recognised organisation with expertise in testing of psychoactive substances applied to the testing methodology, as well as initial screening and confirmation methods, which should be based on different principles of analytical chemistry or different chromatic separations (e.g. first test immunoassay, confirmation gas chromatography).*

- (p) One commentator stated that in case of a positive test the crew member should be referred to a support programme, since it is crucial that anyone with a confirmed positive result is automatically directed towards a support programme and the related peers, in order to get access to advice, help and treatment, in view of a safe return to flight duties.

*EASA agrees and has amended the proposal accordingly.*

- (q) One commentator stated that the case for testing for cause/post-incident or monitoring of adherence to a rehabilitation programme is proven as useful whereas regarding random testing, the case is less clear and there is not a need for this. Rather than conducting random testing, operators should ensure that a strong support programme is in place with an effective peer intervention programme.

*Following the RIA included in this Opinion, EASA agrees and has not mandated random testing to be conducted by the operators. However, the EASA opinion does not prevent any operator from implementing a random testing programme if so deemed necessary, depending on the specific risks to be addressed. The Opinion proposes a multi-layer approach for addressing the safety risks related to psychoactive substance misuse. See Section 2.2.*

- (r) One commentator stated that testing on psychoactive substances upon employment should be removed since this should be covered by the initial and recurrent Class 1 medical examination. The commentator also stated that no testing after an accident or serious incident should be carried out, where the nature of the serious incident excludes a potential influence of psychoactive substances misuse by flight and/or cabin crew.



*EASA maintains its proposal, since testing on psychoactive substances is only conducted mandatorily during initial Class 1 medical examination and not during revalidation/renewal class 1 examination. Therefore, testing should also be carried out upon employment by the operator. Regarding the second part of the comment, EASA agrees and has amended the AMC that now reads '(2) after a serious incident within the meaning of Regulation (EU) No 996/2010, unless there are objective and clear indications that the causes and the consequences of the event are free from any human factor contributor'.*

- (r) Another NAA stated that after having performed a risk assessment, it is believed that within the Member State the prevalence of pilots flying under influence of drugs and alcohol is about 0,3 %, whereas alcohol alone constitutes 0,03 %. Further, it is estimated that the prevalence of commercial airline pilots that abuse alcohol is about 10 %. The latter means about 300 pilots in that Member State alone. The NAA is only made aware of 35 pilots during medical certification every year and testing for influence of drugs and alcohol is infrequently performed by the Police in the Member State. Based on this, the NAA is convinced that within the framework of aviation safety regulations there need to be options for testing. The Member State believes that pilots should be tested frequently and not less than drivers. Currently, there is a large mismatch in the Member State in testing frequency between these two groups. Acknowledging that drugs and alcohol are responsible for a large proportion of road accidents, the Police are aiming at testing 22 % of drivers. Crew members tested during 2015 was only 4 % — from 2012 to 2015 a total of 0 crew members were tested randomly for drugs and alcohol by the Police. The largest operators in the Member State have reported that they have not conducted any random D&A tests of their crew the last years.

*EASA is aware of the different prevalence rates in different Member States. The EASA proposal is consistent with the ICAO Manual and the EMCDDA's 'European Drug Report 2016'.*

- (s) Other commentators doubted that random testing in itself will have a preventive effect. Those commentators cite findings from the US Mandatory Alcohol Testing Program, which show that the prevalence of alcohol violations detected from random testing increased from 0.07 % during 1995–1997 to 0.11 % during 1998–2002 when the annual testing rate decreased from 25 % to 10% (Li et al. Alcohol Violations and Aviation Accidents: Findings from the US. Mandatory Alcohol Testing Program. Aviation Space Environ Med. 2007; 78:510-513). The cost-benefit is therefore questionable.

*The EASA Opinion is consistent with the principle of safety management and in particular with the concept of safety assurance<sup>13</sup>.*

- (t) Other commentators stated that D&A testing should mainly be done at operator level, because EASA acknowledges that in some Member States it might not be possible to extend the privileges of the inspector to conduct alcohol tests. The operators are the body who, through their safety management system, will have the best knowledge of the risk in their population and they could better have systematic programmes and follow-up for a given population. Also, in terms of resources, operators have advantage compared to governmental bodies with

<sup>13</sup> ICAO Doc 9859 Safety Management Manual (SMM) '5.3.3 [...] Safety assurance is accomplished through ongoing processes that monitor compliance with international standards and national regulations. Furthermore, the safety assurance process provides confidence that the SMS is operating as designed and is effective. [...]'



gradually decreasing resources as long as there is a level playing field towards other operators. By requiring random testing to primarily be performed at operator level, we ensure level playing field and contribute to standardisation as this segment is directly under the EASA and NAAs jurisdiction. Ramp inspections should thus be a supplement in cases where NAAs through their risk-based approach identify that an extra level of safety is necessary or for assessing the effectiveness of operators' own programmes to reduce D&A prevalence among crew members. The possibility to conduct D&A testing during ramp inspections is a good support for assuring control of the safety level within national borders. Based on the situation as presented above, and in order for the operator to effectively fulfil the obligation in CAT.GEN.MPA.170 to avoid and prevent the misuse of psychoactive substances, the operators believe it is necessary to require the operator to also have a programme for random testing for such substances. As the requirement for a programme for random testing would apply for a wide range of operators, varying in size and types of operations, one approach could be to require the operators to base their individual test programmes on a risk assessment performed by the operator. The programme and the associated risk assessment could then possibly be scrutinised by the NAA during its standardisation activities.

*EASA maintains its proposal. Random testing by the operator is already possible in some Member States and operators. Under the ICAO Manual, operators and States may require random testing, following a careful analysis of the benefits and drawbacks. The ICAO Manual lists a number of elements that should be taken into account before requiring random testing, e.g. high contacted several operators, known to already conduct random testing of their flight crew. Unfortunately, EASA did not obtain adequate information demonstrating the safety benefits and drawbacks of random testing when conducted by the operator. As described in the RIA included this Opinion, random testing has a number of benefits and drawbacks and there is a need to obtain relevant data from European operators, before proposing a mandatory random testing programme by all EU operators in all Member States. See also Section 2.2 to have a better understanding of how EASA is tackling the risks related to misuse of psychoactive substances. Furthermore, the updated proposal clarifies that nothing prevents an operator from implementing a random testing programme, in order to mitigate the risk that misuse of psychoactive substances remains undetected and endangers the safety of the aircraft or its occupants.*

- (u) One commentator asked if a 'missed test' or a test refusal constitute a positive result, and if it, therefore, triggers an automatic requirement to inform the licensing authority.

*EASA considers that the decision to refer to the medical assessor of the licensing authority should be based on a risk assessment adapted to the case being considered. It is up to the operator to decide whether this would be a reasonable measure as required by CAT.GEN.MPA.170. Situations may vary from one single refusal to systematic refusal. It will also depend on the policy that the operator implements, the enforcement measures foreseen, and the underlying operator safety culture.*

#### **2.4.5. Testing of crew after rehabilitation and return to work**

- (a) Many commentators stated that EASA should not blur the line between support programmes and random testing. They stated that support programmes clearly distinguish between substance abuse programmes and Peer Support/Pilot's Wellbeing programmes. Sometimes



these programmes are completely independent, sometimes substance abuse programmes form part of the Peer Support programmes. Within existing substance abuse programmes, reporting to the authority is regulated already through contracts between the programme, the operator, the pilot involved, and the authority. Outside these programmes, reporting is anyway mandatory 'in case of clearly evident risk to public safety'. Stakeholders stated that it is unclear on what conditions can the pilot support programme screen group members on alcohol and drugs, because this task is normally performed by the NAA or competent law enforcement bodies. It is also not clear for some commentators how the support programmes access and share information. Others stated that the wording 'at least' chosen in the context of random testing inside a pilot support programme is highly problematic and should definitely be removed. Otherwise, it could have a detrimental impact on the effectiveness of a pilot support programme, as it could undermine the trust and support of individual pilots as well as of pilot associations and existing pilot support programme schemes. It must be clear that random testing on drug and alcohol inside a pilot support programme can only be done as part of a follow-up after rehabilitation and return to work. The rule should leave no room for interpretation whatsoever which might encourage any type of random testing done by a pilot support programme on non-participants or on participants that have other than substance misuse issues, such as mental health issues, or other problems. Otherwise, this would discourage pilots from seeking help and undermine trust. Therefore, considering that, the 'at least' (in relation to random testing inside a pilot support programme) must be removed from the regulatory text. In addition, many stakeholders stated that introducing an element of random testing into the pilot support programme is giving the wrong signal and could jeopardise the programme. Using random testing within such a programme can create a situation of mistrust. Stakeholders questioned whether random testing has a place in a pilot support programme. They argued that the wording 'as well as random D&A screening among the pilot support group members' is open to misunderstanding and should be avoided in any future Agency proposals. It must be clear that this is about 'screening among crew members participating in a pilot support programme and as a follow-up following rehabilitation and return to work'. Otherwise, 'members' could be understood as any crew member participating in a pilot support programme having to go through such screening, irrespective of the reason they participate and the issue that is being dealt with. In addition, commentators stated that random drug testing only belongs to the substance abuse 'branch' of a support programme and should never be part of the general procedures of such programmes. Pilots with substance abuse problems are always referred into support programmes having their own internal rules — including random testing while and after treatment. If test results are positive these results — as the respective contracts state — are reported to the authority anyway.

*EASA agrees and has amended the proposal accordingly.*

#### **2.4.6. Pilots' psychological assessment — Role and responsibilities of operators**

- (a) Feedback received questioned the introduction of a psychological assessment. Some stakeholders stated that they are in favour of introducing a psychological assessment in the pre-employment selection process. Several commentators supported psychological/psychiatric assessment by operators. Some stated that the value of such an assessment is likely to be limited in regard to sensitivity for detection of relevant psychiatric condition. Mental health



problems may also occur at a later stage in the career. On the other side, such measures may strengthen the attention on mental health problems. It also seems credible that such screening may help in identifying some of the relevant psychiatric cases. Others stated that, at present, no convincing data exists to support that adding psychological testing to the hiring process or to the routine medical examinations enhance the ability to assess the mental fitness of the pilot workforce. Commentators stated that the assessment should only be done during the Class 1 medical examination. Requiring this during the operators' hiring process is a duplication, because there is no scientific proof that an assessment of a possible interference with the safe operation of the aircraft could be done differently from one type of work environment to another, or that CAT operators have significantly different work environments.

*EASA maintains its proposal to require a psychological assessment before commencing line flying since this is a proactive measure that will enhance safety and is based on existing International Air Transport Association (IATA) Guidance Material. However, the proposed IR and GM have been amended to clarify the intent of the psychological assessment, which is to identify psychological attributes and suitability of the flight crew in respect of the work environment of the operator and to reduce the likelihood of negative interference with the safe operation of the aircraft.*

- (b) Some stakeholders stated that the role and type of psychologists to carry out interviews, psychometric assessments and tests for an airline at the different stages of the selection process should be better specified. Feedback received from stakeholders also showed concerns about the availability of psychologists with knowledge in aviation. Some stated that where no psychologists with acquired knowledge in aviation are available, the authority should ensure adequate training is carried out within a reasonable time frame. They questioned what would be the competency requirements for the psychologist and stated that there is no European standard for such a psychologist. Commentators requested the proposal to be less specific and more performance-based. Otherwise, they stated the proposal creates too much burden for the NAA. An initial text that foresaw that the psychologist should be accredited or registered was deemed to be too burdensome, since in many Member States, psychologists are neither accredited nor registered. Commentators also provided feedback on the qualification requirements of the psychologist. While some commentators stated that there should not be any qualification requirements, most commentators stated that qualification requirements are necessary, citing the IATA Guide page 39, which mentions 'involvement of a qualified aviation psychologist or a qualified aviation human factors expert is essential to the interpretation of all data and to the maintenance (evaluation) of the selection system'. Commentators were of the opinion that, given the importance of this psychological assessment for safety, both for the pilot and for the recruiting operators, this assessment should not be carried out by psychologists who do not have relevant expertise in aviation. If this expertise is missing, the prediction will probably be of low quality, imprecise or wrong. This would seriously undermine the value of this mitigating measure. The basic requirement must therefore be 'aviation psychological expertise' — with an additional provision that ensures adequate training is carried out as soon as possible to fill potential skill-gaps in the market of psychologists.

*EASA has amended the proposal deleting any reference to the psychologist being registered or accredited. In the proposal it is specified that the psychological assessment should be directly*



*performed, or overseen and validated, by a psychologist, with expertise in the psychological selection process of aviation personnel and knowledge of the flight crew's aviation operating environment. This means that, for each assessment, the presence of a psychologist is not required, as long as the process is overseen and validated by a psychologist.*

- (c) Some commentators requested an approval of the psychologist by the authority. While indeed this would entail a certain administrative burden, there should be a body or authority that oversees what kind of experts airlines use. This body or authority would then have the authority to accept experts or to reject them. It is crucial that only registered and very well-qualified psychologists with adequate operational aviation experience and expertise are being involved, as not doing so could actually do more harm than good. Hence, an approval also obliges the authority to take an active interest in this, which will be beneficial for any subsequent oversight to be performed. Therefore, the commentator stated that it is important that the operator uses suitably qualified psychologists, that: a) hold an MSc in psychology; b) are registered at the national psychologists' association and have signed for adhering to the ethical code of conduct of psychologists (or have the EuroPsy<sup>14</sup>); c) are trained and experienced in the psychological selection process of pilots (safety-sensitive aviation personnel); and d) are European Association for Aviation Psychology (EAAP) accredited as aviation psychologists. The authority should audit if the operator is using such a psychologist and fulfilling these requirements. In some countries, aviation psychologists might currently not be available. In that case, the authority should ensure adequate training to be available to motivated local psychologists. Here, the EAAP can support training.

*EASA maintains its position that an approval of the individual psychologist would be too burdensome and not proportionate. Requiring a prior approval of the psychologist is not in line with a performance-based approach to regulation. Additionally, the recognition of professional qualifications, outside the scope of the Basic Regulation, does not fall under the responsibility of EASA. EASA relies on Directive 2005/36/EC<sup>15</sup> to facilitate the recognition of the professional qualifications of psychologists.*

- (d) Many commentators argued about the need to harmonise practices validated by the competent authority. They stated that a psychological assessment at the level of Part-MED must not be confused with recruitment actions/selection conducted by the operator.

*EASA confirms and further clarifies that the assessment should only assess the personality of the flight crew to ensure a valid prediction of responsible and safe behaviour of the pilot in respect of the work environment. The aim is not to mirror the Class 1 assessments, but rather to ensure that the specific challenges of the operator are duly reflected in the recruitment process.*

- (e) Some commentators stated that it is for the operator to determine the relevance of the psychologist's knowledge with reference to the operator's particular operational environment.

*EASA maintains its proposal and is of the opinion that without any knowledge regarding the flight crew's operational environment, the outcome of the assessment would not be suitable for the operations.*

<sup>14</sup> European qualification standard for psychologists

<sup>15</sup> Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005 p. 22) (<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32005L0036&qid=1480403236659>).



- (f) Some stakeholders stated that the proposal should ensure a high-quality performance of testing. The psychological assessment should not only be overseen and validated by accredited or registered aviation psychologists, but also performed by them.

*EASA considers that the proposed text allows for both options, i.e. the psychologist may either perform themselves the assessment or determine the extent to which they actually need to be conducting the various steps of the assessment depending on tasks to be performed, the means and resources available, and the competence of the personnel involved. This makes the regulatory proposal more flexible and performance-based.*

- (g) Some commentators stated that the psychological assessment should not only happen before commencing line flying, but also as part of the initial training. They argued that this will ensure that approved training organisations (ATOs) consider this as an element to be introduced into their programme, and — ideally — to do so before their ‘clients’ have spent significant amounts of money to the ATO for their training. It would help ATOs consider themselves as part of the ‘responsibility chain’. Moreover, it would help mitigate the socio-economic aspects and pressures on young (deeply indebted) pilots, which might otherwise push them into hiding or denial of mental health problems.

*EASA clarifies that the psychological evaluation performed before commencing airline line flying is intended to select, based on their attributes, the best suitable pilots for a specific airline. The screening for possible or evident risks related to pathology is performed at initial class 1 medical examination. For a specific operator, the selection and psychological evaluation performed by a pilot training organisation would only be meaningful if the process includes the operator-specific requirements and selection criteria. This may be the case for training organisations managed by an airline. However, most of pilot training organisations provide initial training to self-sponsored candidates and these training organisations are independent from any particular air operator. Most of pilot training organisations conduct psychometric tests related to cognitive and psychomotor abilities with little consideration for social interactional competences and personality traits that are more relevant for an airline. Therefore, an operator should conduct an independent psychological evaluation of the airline pilot before recruitment. Airlines know how past experience, in recruiting pilots, has been effective in appointing the most suitable individuals. Furthermore, operators have the possibility to collect and process data through the career path of a pilot and to identify the most statistically-significant indicators. They know best how the structure, the management style, and the organisational culture affect their personnel. During a psychological evaluation, operators typically assess personality traits and social abilities with regard to anticipated work conditions, particularly the stress factors and the challenges stemming from their operational environment. To summarise, air operators can monitor their selection system and improve their programmes over time, while training organisations are much less effective in anticipating the operational environment of a specific airline. EASA considers that the ultimate responsibility for the selection of safety-sensitive personnel, before assignment to flying duties, rests with the air operator.*

- (h) One stakeholder requested to include an assessment of how the flight crew deals with operational and financial/socio-economic pressures. Given the growing prevalence of atypical employment forms — and the operational and financial/socio-economic pressures that may arise from that — the text should be adapted accordingly.





*The EASA proposal takes into account the operational environment of the operator, including financial/socio-economic aspects.*

- (i) Several stakeholders disagreed with the proposed AMC that referred to an assessment of personality traits, arguing that other examples than the ones listed in the regulatory proposal could be suggested as well. They stated that the current list of ‘traits’ is restrictive and, therefore, not adequate. Said list contains some traits, some competences, motivation, and a subjective element. Furthermore, there is no mention of cognitive abilities (such as attention, reasoning, memory) or psychomotor abilities. One stakeholder stated that rather than assessing personality traits, the AMC should assess the personality of the flight crew to ensure a valid prediction of responsible and safe behaviour of the pilot in respect of the work environment.

*EASA has amended the proposed IR and AMC. The intent of the psychological assessment has been moved to IR, whereas examples of an assessment of psychological attributes has been moved to GM, which refers to the Guidance from IATA. This clarifies the intent of the rule and provides the necessary flexibility.*

- (j) One commentator requested to clarify that the psychological assessment mentioned in CAT.GEN.MPA.175 is not a clinical psychological assessment.

*EASA agrees that this should be clarified and has included this clarification in the proposed GM, which now states that a psychological assessment performed by or on behalf of an operator should not be considered or conducted as a clinical psychological evaluation of mental fitness.*

- (k) One commentator requested to know if a crew member who has been psychologically assessed before commencing line flying has to undergo such an assessment again if they move from one operator to another.

*EASA has issued a guidance to clarify how an assessment made by an operator can be subsequently accepted by another operator.*

#### 2.4.7. Support programme

- (a) Most commentators provided positive feedback on the EASA proposal on support programmes. Stakeholders stated that support programmes might help reduce under-reporting. A support programme could raise awareness of the problem and encourage crew members to seek help and support when needed. This could also positively affect crew members withholding information about use/misuse of psychoactive substances or psychological/psychiatric problems. Other commentators stated that a support programme is one of the solutions to help pilots in problematic situation, but it is suggested that emphasis be put on the importance of the role of the operator in implementing the appropriate just safety culture backing up such programmes. Commentators also welcomed the acknowledgement that operators do not have to establish a support programme from scratch, but can rely on third-party providers of support programmes. One commentator stated that if cabin crew are to be included in testing for psychoactive substances, then they have to be part of the support programme in the same way as flight crew.

*While EASA understands the request to also include cabin crew into the mandated scope of a support programme, at this moment, EASA acknowledges that moving towards a support programme might be a new concept for many operators. EASA therefore supports a phased*



approach, starting with flight crew. As operators, NAAs, and EASA become accustomed to the benefits of support programmes, an extension of support programmes to cabin crew is supported. Furthermore, it should be noted that, while the Agency current proposal does not explicitly require cabin crew to be included in support programme, the proposal does not prevent any support programme from providing support to cabin crew, or any other aviation safety-sensitive personnel, as well. As already explained, the first step proposed by EASA addresses issues mainly related to class 1 aero-medical certification.

- (b) One commentator stated that more guidance is needed regarding support programmes.

*EASA is aware that support programmes are a new concept for many operators and has therefore proposed an extended transition time of 24 months. During this time, stakeholders will share best practice and advise on how to set-up a functioning support programme. EASA is aware that, in Canada and the USA, support programme in its various forms has been widely recognised and utilised since the 1970s. The experience gathered ever since is documented and available today.*

- (c) One commentator stated that the GM on the support programme should also include an offer of motivating alternative positions to flight crew in case a return to in-flight duties is not possible. Limitation of the financial consequences of a loss of licence, for example through extending loss of licence insurance coverage, are to be considered labour issues and should not be included in GM to the Air OPS rules.

*EASA maintains its proposal, given the BEA recommendation, to also address fear of loss of licence.*

- (d) One commentator stated that the exchange of data between the operator's management system and the support programme should specify clearly that data can only be used in an anonymised and aggregate manner.

*EASA agrees and has amended the proposal accordingly.*

- (e) One commentator stated that GM should be developed to ensure that joining a support programme does not remove the aircrew member's obligation to seek aero-medical advice in cases of decrease in medical fitness in accordance with MED.A.020 of the Aircrew Regulation.

*EASA agrees and has amended the proposal accordingly.*

- (f) One commentator stated that the any reference to fear of loss of licence should be removed. They argued that fear of loss of licence — that is, work — relates to all aviation professions so this issue should not be put in the regulation for a single profession only. They also stated that this issue is much bigger, the basis of risk management rises from the operators' personnel policy, occupational health, society's social policy, work pension insurance and voluntary insurance.

*EASA maintains its proposal, given the BEA recommendation to also address fear of loss of licence as one of the areas covered by a support programme or by the operator.*

- (g) One commentator stated that there should be a reporting system to the medical assessor of the licensing authority in clearly defined cases (e.g. severe medical or safety issues).



*EASA has included a reporting system to the AME. The proposed GM states that joining a support programme does not remove the flight crew member's obligation to seek aero-medical advice in case of a decrease in medical fitness in accordance with MED.A.020 of the Aircrew Regulation.*

- (h) Some stakeholders stated that the importance of the role of the peers in a support programme should be emphasised more forcefully in the proposal. Support programmes need to be in the hands of independent pilots. Neither the operator, nor the union, nor the authority, nor any specialist like a psychologist, a medical doctor, an AME or a lawyer should be able to take over the responsibility for the team. The perceived independence of these programmes by pilots in need is of utmost importance. A pilot organising the programme is the visible sign of independence and trust into that structure. This pilot needs the specialists in the background and for any referral, but the specialists should never be in the leading role. Recent experience in different European countries demonstrated the difficulties the specialists run into even if somehow familiar with the field of aviation. The best solution would be to have a requirement is run by pilots. They stated that the term 'peer' was unfortunately deleted from the originally proposed 'peer support programme' (probably as the support programme is a wider term, potentially including peer support programmes). However, the involvement of trained peers is one of the most important keys to success of any support programme. It is therefore crucial that explicit reference is made to peers and peer support structures, to ensure that operators facilitate the active involvement of peers and peer support structures (be it in-house or third-party structures, such as Mayday Foundation or similar programmes).

*EASA has included the reference to peers in the proposal related to the support programme.*

- (i) One commentator stated that the AMC on the meaning of the support programme should not only mention self-declaration, but also referral by a crew colleague as a means to ensure access to a support programme. The commentator stated that referrals by fellow crew members is the 2nd most likely way of access to a support programme.

*EASA agrees and has amended the proposal to highlight that access to a support programme should enable self-declaration or referral in case of a decrease in the flight crew member's medical fitness.*

- (j) One commentator stated that while a support programme is a good idea, the consequences of such programmes should not compromise flight safety by creating a free haven for declaration of serious medical conditions which are withheld from reporting to AME/AeMC and AMS. The NAA should be informed about any health issues that might affect the flight safety.

*EASA agrees and has clarified that notwithstanding the provisions related to confidentiality and data protection, an agreement with related procedures should be in place between the operator and the support programme on how to proceed in case of a safety concern.*

- (k) One commentator stated that the GM listing the essential elements on how to ensure trust between the airlines' management and crew members should be transferred to an AMC level instead of the current GM level.

*EASA maintains its proposal, which is in line with similar provisions in the Air OPS rules regarding flight data monitoring, where the trust between the airlines' management and crew members is also important and contributes to the success of the system. The proposed GM*



*(GM2 CAT.GEN.MPA.215 Support programme) clearly states that essential trust between management and crew is the foundation for a successful support programme. This trust can be facilitated by establishing a platform for multi-stakeholder participation and partnership in the governance process, involving flight crew representatives from one or more operators, representatives of the relevant operator and, possibly, representatives of the NAA.*

- (l) One commentator stated that the proposal on how the operator informs the NAA about a pilot in the interest of public safety should be rewritten to cater for the scenario, whereby it is sometimes required that information on the identity of an individual be released to the operator in order for that individual to be properly covered by a sick leave programme. This procedure is usually agreed by the support programme and management as part of the support programme in question. Therefore, the AMC should be amended to read ‘agreement should be in place between the operator and the support program on how to react’.

*EASA agrees and has revised the GM that now states that mental health professionals involved in the support programme and dealing with flight crew should be trained on cases where information should be disclosed due to an immediate and evident safety threat and in the interest of public safety. In addition, a separate GM states that in case of a confirmed positive test, an agreement should be in place between the operator and the support programme on how to react to a safety threat.*

Done at Cologne, 8 December 2016

Patrick KY  
Executive Director



### 3. Regulatory impact assessment (RIA)

#### 3.1. Introduction

The current RIA integrates the analyses of the RIAs performed in the context of two draft Opinions and Decisions:

- Draft Opinion and Decision ‘Aircrew medical fitness — Implementation of the recommendations made by the EASA-led Germanwings Task Force on the accident of the Germanwings Flight 9525 (Drug and alcohol testing)’
- Draft Opinion and Decision ‘Aircrew medical fitness — Implementation of the recommendations made by the EASA-led Germanwings Task Force on the accident of the Germanwings Flight 9525 (Changes to Regulation (EU) No 965/2012)’

The above-mentioned integration was decided by EASA in order to:

- address the Task Force recommendations in the Air OPS domain in a holistic manner. This will guarantee that the cumulative overall impact of the individual regulatory proposals in said domain is considered in the final decision;
- enhance the transparency of the decision-making process and the quality of the final opinion, while taking into account stakeholders’ input and feedback on the individual regulatory proposals; and
- analyse the overall impact of the regulatory proposals while combining different policy options and exploring their synergistic effect.

The RIA conducted as regards amendments to the Aircrew Regulation has not been considered in this opinion, as it has already been published as part of EASA Opinion No 09/2016 ‘Update of Part-MED (Annex IV to Commission Regulation (EU) No 1178/2011)’.

Therefore, this RIA addresses the following recommendations in the Air OPS domain.

**Table 1 — Overview of the recommendations in the Air OPS domain**

Task Force recommendation No <sup>16</sup>	Air OPS Addressed in this Opinion through
2	Psychological assessment of flight crew by CAT operators
3	CAT operators’ prevention of aircrew misuse of psychoactive substances
6	Flight crew support programme

<sup>16</sup> <http://www.easa.europa.eu/newsroom-and-events/news/report-task-force-germanwings-flight-9525-european-commission>



### 3.2. Background

The Germanwings Task Force recommends to mandate D&A testing as part of a random programme at least in the following cases: initial Class 1 medical assessment or when employed by an airline, post-incident/accident, with due cause, and as part of a follow-up after a positive test result.

Unannounced testing following rehabilitation and return to work is assessed as one option of random testing in this RIA.

Regarding the misuse of psychoactive substances, the Aircrew Medical Fitness Workshop and Conference in 2015 and 2016<sup>17</sup> revealed that stakeholders supported testing in all of the above-mentioned cases. Especially unannounced testing as part of a follow-up in the context of a pilot support programme, is widely approved by addiction specialists, operators and pilots. However, as regards 'purely' random testing by the operator to detect alcohol or drugs, stakeholders' opinions were divided. Some suggested that this should be mandated by the Air OPS rules, whereas other stakeholders suggested that the advantages and disadvantages of the different random testing options should be assessed separately.

### 3.3. Safety issues in the random D&A testing conducted by operators

Li et al. (2007) assessed the proportion of aviation accidents attributable to alcohol as 0.13 % in the period 1995–2002. Canfield et al. (2012) extracted data from the FAA toxicology database for all pilots who died from 2004 to 2008 in aviation accidents. Alcohol was identified in 7 % of the population tested. No pilot flying for a US CAT operator was found to be flying in violation of FAA alcohol regulations. Two airline transport pilots were found to be taking medications; one had diphenhydramine in his system, and another was found to have acetaminophen in his system.

Already today, CAT.GEN.MPA.100 stipulates that a crew member shall not perform duties on an aircraft when under the influence of psychoactive substances or alcohol.

In addition, in accordance with AMC1 CAT.GEN.MPA.100(c)(1), the operator should issue instructions concerning the consumption of alcohol by crew members. The AMC also specifies that the instructions should be not less restrictive than the following:

- (a) No alcohol should be consumed less than 8 hours prior to the specified reporting time for a flight duty period or the commencement of standby.
- (b) The blood alcohol level should not exceed the lower of the national requirements or 0.2 per thousand at the start of a flight duty period.
- (c) No alcohol should be consumed during the flight duty period or whilst on standby.

However, the Air OPS rules applying to CAT operators do not explicitly mandate any random testing policy either via the European ramp inspection programme or by the operator in order to ensure that a crew member under the influence of psychoactive substances does not endanger the safety of the aircraft or its occupants. However, nothing prevents an operator already today from applying a random testing policy in line with CAT.GEN.MPA.100.

<sup>17</sup> <http://www.easa.europa.eu/easa-and-you/aircrew-and-medical/follow-up-germanwings-flight-9525-accident>



The impairment of a crew member due to the misuse of psychoactive substances is often difficult to detect and can substantially increase risk-taking behaviours. Therefore, despite the current set of rules, a crew member adversely affected by undetected misuse of psychoactive substances may access the aircraft and be assigned operational duties while they are likely to endanger safety of flight. Therefore, testing on suspicion is an important mitigating measure.

National legislations regarding random D&A testing vary largely across EU. Each country has a specific structure, legal scene and approach<sup>18</sup>. In some Member States, random D&A testing is exclusively performed by the police while in other Member States random testing is not foreseen. In many Member States, 'purely' random testing of employees by the employer is regulated by data protection and privacy rules and is often not allowed. The legal basis for the conduct of 'purely' random tests by the operator might therefore be challenged by national privacy and employment laws.

### 3.4. Advantages and disadvantages of random testing

#### 3.4.1. Advantages of random testing

- (a) One of the primary benefits of random testing is that it has a proactive deterrent effect on the decision to misuse psychoactive substances.
- (b) Random testing has minimal selection bias and uses an objective method.
- (c) The use of random testing shows zero tolerance for alcohol and drugs misuse from the regulator's perspective.
- (d) Another benefit may be public trust. Some people hold the opinion that the possibility of even one occurrence of misuse of psychoactive substances in aviation justifies imposition of a programme on all ('One is one too many if it's my pilot'). It will increase the trust of the general public and politicians in the aviation system.
- (e) In addition to its deterrent effect, random testing may provide data for answering important research questions. Analysis of random testing data can help estimate the point prevalence rates of alcohol violations among airline employees with safety-sensitive functions by occupation and over time. The results of the study are valuable for monitoring alcohol violations in aviation employees and for programme evaluation and policy reform (Li et al. 2007).
- (f) Random testing is a valuable tool in the context of alcohol and drug treatment and rehabilitation programmes. In such programmes, unannounced testing will be carried out when an individual has been treated for misuse of alcohol or drugs. There is convincing evidence that this form of random testing is essential to maintain this person's abstinence from alcohol or drugs.

#### 3.4.2. Disadvantages of random testing

- (a) Low cost-effectiveness when comparing the violation rate with the costs, and operational problems (logistics, replacement of crew), while ICAO experts from around the world agree that education is

<sup>18</sup> 'Prevention of alcohol and drug use in the workplace' Pompidou Group International Conference, Strasbourg, 15 and 16 October 2014 ([https://www.coe.int/T/DG3/Pompidou/Source/Activities/Workdrug/P-PG-Work\(2014\)7\\_meeting\\_report\\_en.pdf](https://www.coe.int/T/DG3/Pompidou/Source/Activities/Workdrug/P-PG-Work(2014)7_meeting_report_en.pdf))



the single most important tool in preventing misuse of psychoactive substances, and dependents of alcohol or drugs are best identified by co-workers and supervisors (ICAO, 1995) or after information on driving while intoxicated (DWI) convictions (Mc Fadden, 1997). It appears that use of alcohol or illicit drugs is very rare as a causal or contributory factor to accidents in which airline pilots (Class I airline pilots) are involved (Canfield et al., 2012). Drug violations are especially rare in flight crews; on average, it takes about 2 000 random tests to detect one drug violation (Li et al., 2011).

Data from random D&A testing programmes show a low violation rate as regards alcohol use. The FAA random alcohol testing from 2006 till 2014 shows a mean annual violation rate of 0.106 % (data retrieved from Federal Registers 2007–2015 — DOT, USA). For drug testing, the yield appears to be somewhat higher: from 2006 to 2014, the mean annual random drug test positive rate was 0.524 % in the FAA programme, which covers flight crew, flight attendants, flight instructors, aircraft dispatchers, maintenance personnel, aviation screeners, ground security coordinators, and air traffic controllers. Violation rates for drugs were highest for maintenance personnel (1.00 %) and aircraft screeners (1.16 %) and lowest for flight crew (0.05 %) (Li et al., 2011).

- (b) Mandatory testing is not currently justified by evidence (Jordaan, 2015). The question whether misuse of psychoactive substances poses a potential or current risk to the aviation workplace, is difficult to answer. Data on a causal relationship between misuse of psychoactive substances and accidents or incidents is scarce and difficult to interpret. Specimens from fatally injured pilots may be putrefied and the alcohol could have been produced post-mortem. Moreover, drugs may be identified, but a direct relation with impaired performance will be difficult to demonstrate. In their reasoning, the Task Force referred to an abstract of a conference presentation of Mitchell and Lillywhite (2013) in which 31 medical-caused fatal CAT accidents worldwide were reported (average rate 1 per 100 million hours). In 24 (77 %) of these accidents, causes were related to psychiatric conditions including illicit/psychotropic drugs and alcohol. Because important causal and methodological details are not described in this abstract, the interpretation of the results remains rather speculative. Canfield et al. (2012) extracted data from the FAA toxicology database for all pilots who died from 2004 to 2008 in aviation accidents. Alcohol was identified in 7 % of the population tested. No airline transport pilot (flying CFR Part 121) was found to be flying in violation of FAA alcohol regulations. Two airline transport pilots were found to be taking medications; one had diphenhydramine in his system, and another was found to have acetaminophen in his system.

Li et al. (2007) assessed the association between alcohol violation and accident involvement by contrasting the FAA random testing data with post-accident testing data. Out of the 1 821 post-accident tests performed during the study period, 4 (0.22 %) had blood alcohol concentrations (BACs) of 0.04 %. The estimated odds ratio (OR) of accident involvement associated with alcohol violations was 2.56 (95 % confidence interval 0.81–7.08). Given the estimated OR (2.56) and violation rate from random testing (0.09 %), the proportion of aviation accidents attributable to alcohol violations was estimated to be 0.13 %.

It is concluded that a risk analysis to support the recommendation for mandatory random testing is currently difficult to perform due to the scarcity of useful data. More data and information sharing is





needed to characterise the extent of the problem. This might be enabled by sharing anonymised information currently at the disposal of support groups.

- (c) Absence of performance-impairing residual effects of alcohol. Use of alcohol by pilots shortly prior to their flight is rare in commercial air transport. However, harmful use of alcohol in the evening prior to a next-day flight is probably far more common practice (e.g. Modell & Mountz, 1990; Cook, 1997; Maxwell & Harris, 1999; ICAO, 1995; Simons & Valk, 2003). Pilots with residual effects of alcohol ('hangover') form an insidious danger for flight safety as these effects may cause subtle incapacitation which may not be noticed by other crew members. Alcohol will also disturb preflight sleep which presents an additional hazard to flight safety. Significant residual effects (also called 'hangover', 'carry-over' effects) on piloting skills, which have been described in literature, are summarised in Table 2. These pilots will not be detected with random breath analyser testing, because in 'the morning after the night before' they will have no alcohol in their blood or breath (BAC will be 0.0 %; Simons & Valk, 2003). In a survey of the Dutch scientific institute TNO (Simons & Valk, 2003), 5 % of the pilots of a charter company (n=302) admitted to experience adverse effects of 'evening' alcohol in the next morning when they had to fly. This group of pilots will not be identified by random alcohol testing. Prevention of hangover effects of alcohol can only be achieved through stimulating aircrew's awareness and low-threshold entrance in a support programme.

**Table 2 — Results from literature on residual effects of alcohol on flight-related performance. Hangover time periods are indicated under 'measured after'. BAC=blood alcohol concentration (%). ATC=Air Traffic Control (Simons & Valk, 2003)**

<i>author(s)</i>	<i>evening BAC</i>	<i>type of tasks</i>	<i>effect on performance</i>	<i>measured after</i>	<i>BAC</i>
Yesavage & Leirer (1986)	0.1 %	simulated flight	impairment	14 hrs	0 %
Morrow et al. (1990)	0.1 %	radio communication	impairment	8 hrs	0 %
Morrow et al. (1991)	0.1 %	simulated flight	impairment	8 hrs	0 %
Morrow et al. (1993)	0.1 %	simulated flight	increased variability	8 hrs	0 %
Taylor et al. (1994)	0.08 %	ATC communication	impairment	8 hrs	0 %
Yesavage et al. (1994)	0.08 %	simulated flight	impairment	8 hrs	0 %
Taylor et al. (1994)	0.08 %	simulated flight	no effect	8 hrs	0 %
Simons & Valk (2003)	0.007 %	tracking & vigilance	& impairment	9 hrs	0 %



- (d) As for random drug testing, the following considerations apply: 1) Drug tests provide information about recent use of drugs, but drug tests do not identify continued substance use disorders or physical dependence, although after a positive test the pilot is likely to undergo intensive medical screenings; and 2) a test for psychoactive substances other than alcohol does not provide 100 % evidence of current impairment. Unlike alcohol testing, where a certain blood alcohol level is a significant indicator of impairment, a particular concentration of other psychoactive substances or their metabolites in a person's body cannot be directly correlated to a particular degree of impairment (ICAO, 1995). Impaired performance can only be shown with cognitive performance tests.
- (e) Testing for specific prescription or over-the-counter (OTC) medications is not feasible in a standard setting, because each medication needs a specific test in a dedicated laboratory. In a TNO survey, it was found that out of 302 pilots of a commercial charter airline, 13.8 % used prescription drugs and 5 % used OTC drugs<sup>19</sup> that are considered potentially harmful for flight safety (Simons & Krol, 2003). In general, applicants will have no reserve to mention prescription and OTC medication to the AME. However, with regard to use of antidepressants, this might not always be the case, because an applicant might try to hide a depressive illness. Screening for antidepressants might be considered by the authorities, but it should also be considered that pilots who have recovered from depressive illness may be certificated for flying whilst continuing to take antidepressants, such as citalopram, sertraline and escitalopram. Guidance on drugs to be tested may need frequent updates.
- (f) Deterrence will only occur within a group of occasional users and not in dependents or addicts (ICAO, 1995). Special consideration should be given to random testing for alcohol, which may be less useful to deter alcohol dependents than occasional users for two reasons. Firstly, alcohol is processed out of an individual's body fairly rapidly, so unless an employee has an extremely high BAC upon arrival at work or continues to drink after arriving, there is only a narrow time window during which the BAC would be detectable. Once an employee escapes detection, the deterrence value of a random testing programme is diminished for that person and anyone who knows of the escape. Secondly, in the normal progression of drug dependence of the alcohol type, the workplace is generally the last part of the employee's life to be affected by alcohol use. Therefore, by the time the employee's use of alcohol is likely to be detected on a random test, the employee has probably become too dependent to be deterred by the existence of a random testing programme.
- (g) Random testing may help drive problems underground and can undermine support programmes. Individuals might fear negative consequences and try to hide their mental problems including substance use disorder or medication use, and this might lead to the progression of disorders to more severe stages (Büringer, 2015). Substance dependents are very intelligent and creative in avoiding detection. In case of random testing, it is expected that most pilots are clever enough to refrain from alcohol in the 8- or 10-hour bottle-to-throttle period. This represents a safety problem, because they may be flying while under the influence of alcohol withdrawal symptoms such as cognitive decline. These are the crew members who buy alcohol directly after landing.

<sup>19</sup> Over-the-counter = self-medication.



- (h) Random drug testing has significant false positive rates caused by the use of approved prescription and OTC medication, food (e.g. bread with poppy seed), environmental contamination (e.g. Tetrahydrocannabinol (THC)), and methodological limitations. A statistical principle is that in a population where the prevalence of psychoactive substance use is low, such as pilots, a highly sensitive test (such as most drug tests) will inevitably show significant false positive rates. Investigators found rates of false positive results (22 % of opioids, 46 % of methadone, 21 % of amphetamines, 61 % of benzodiazepines, 12 % of cocaine, and 21 % of marijuana) identified as positive on point of care (POC) screening tests but negative on laboratory tests using LC-MS/MS (Liquid Chromatography-Mass Spectrometry) (ASAM, 2013). There is a concern with false positives where valuable flying time will be lost while a second test is conducted to confirm that it was a false initial positive. Should blood testing be required for confirmation of an initial test, results from these can take longer than 32 days (CASA, 2006). The economic and social impact of unjustified grounding of pilots due to false positive tests has to be taken into account from an economic and social point of view.
- (i) Random drug testing has significant false negative rates. POC testing in addiction treatment settings found high rates of clinically false negatives, that is, samples tested at POCs were reported negative but laboratory LC-MS/MS results were positive. 29 % of opioids, 28 % of methadone, 43 % of amphetamines, 35 % of benzodiazepines, 40 % of cocaine, and 20 % of marijuana identified by LC-MS/MS were missed by POC tests (ASAM, 2013).
- (j) While random testing and reasonable suspicion testing complement each other, the aim should be to increase the likelihood of fellow crew members reporting on pilots with an issue of misuse of psychoactive substances. This can be better achieved via support programmes rather than random testing.
- (k) Products to defraud or ‘beat’ random testing are available on the market. Some 400 products are marketed on the internet and in drug-culture magazines with the objective of producing drug-free results.

#### Controversial issue

- (l) In some cases, there is little robust evidence on the deterrent effects of random drug testing for either illicit drugs or alcohol in the work place (Australian Safety and Compensation Council, 2007).

### 3.5. Overview of the comments received

As mentioned above, the current document reflects the comments received during technical consultation with Advisory Bodies of the draft Opinion and Decision on drug and alcohol testing and the draft Opinion and Decision on changes to the Air OPS Regulation.

As regards the RIA on drug and alcohol testing, stakeholders' main concerns were focused on:

- Alcohol screening of flight crew during ramp inspections for EU and third countries: The stakeholders are concerned how the third-country operators might respond to alcohol tests embedded in the ramp inspection programme. They are concerned that those tests lead to delays and can negatively impact on the pilot's performance. EASA acknowledges that a transition period



for full deployment of the procedure is necessary and is proposing a transition period of 24 months for the whole regulatory proposal, including alcohol testing within the ramp inspection programme. After this date, alcohol tests would be embedded into the ramp inspection programme. The AMC/GM associated with the proposed changes at IR level, clearly specify that those Member States that conduct random alcohol test via law enforcement officials, may continue to do so. In this case, the data collected from confirmed positive tests should be included into the European database of ramp inspections, without specifying the name of the aircrew member. The ramp inspection programme as part of ARO.RAMP includes many safeguards that ensure that inspections should not cause unnecessary delay and that inspectors are trained. Alcohol tests can be conducted very quickly and should not take more than 12 minutes. The RIA also includes forecasted costs for compulsory training of ramp inspectors to conduct alcohol screening, which is a supplementary measure to ensure a harmonised implementation of the additional task. In addition, some Member States contested the possibility to conduct alcohol screening during ramp inspection due to the conflicts with the national regulatory system. They proposed a system without mandatory provisions, providing the freedom to conduct random alcohol screening at any time during duty time of the crew, no predetermined rate of random alcohol checks, and a clear reference to national methods for alcohol testing. EASA, in this Opinion, clarifies that ramp inspections shall contain alcohol tests, but that this should be based on a risk assessment.

- Re-examination of the economic impact, and more specifically inclusion of costs, related to flight delays due to testing of crews and false positive test results and the consequences for the pilot whose tests are positive: In response, EASA reminds stakeholders that unlike drug tests, alcohol tests have a very low rate of false positive tests. A positive alcohol test via a breath analyser will most likely lead to a positive confirmation test. Regarding the costs, their impact would not affect significantly the overall economic impact (medium negative impact). No major delays are expected in the whole inspection because ramp inspectors will be trained to conduct the screening within the timeslot for ramp inspections and since alcohol testing as such only takes 12 minutes. Therefore, the ramp inspection is not expected to cause any significant delays unless the pilot is under the influence of alcohol and should not fly. As regards the testing, the costs related to a second confirmation test are included in the economic impact assessment. With the overall violation rate for pilots being 0.091%<sup>20</sup> and a very low false positive rate (0.04%<sup>21</sup>), the economic impact of false positive test results is negligible. As a consequence, the costs for cancellation of flights are not considered in the economic analysis. A detailed analysis, justifying the negligibility of the impact of the false positive test result is provided in Appendix 3 to the RIA.
- More justification on the overall medium positive safety impact for the policy option 'Alcohol screening of flight crew during ramp inspections was requested. It has been noted that the FAA data of 2011 showed an overall violation rate for pilots of 0.044 %. Hence, tests during ramp inspections are considered by some stakeholders to not contribute substantially to aviation safety. EASA clarifies

<sup>20</sup> In 2013, the random alcohol test violation rate was 0.091 % according to the FAA data.

<sup>21</sup> New Zealand's breath and blood alcohol testing programs: further data analysis and forensic implications, *Forensic Sci Int.* 2008 Jul 4;178(2-3):83-92. DOI: 10.1016/j.forsciint.2008.02.005. Epub 2008 Mar 26.



that despite a very low yield, safety will be influenced positively, because of the deterrent effect and because ramp inspection checks apply also to third-country operators, not only to EU operators. Furthermore, EASA considers that alcohol screening, as part of ramp inspection programmes, enables the Member States to enforce compliance with the Standardised European Rules of the Air<sup>22</sup>, at least as regards the risks related to the misuse of alcohol.

As regards the RIA on the proposed changes to the Air OPS Regulation, the main concerns were focused on:

- Feasibility of the economic costs, regarding the policy option ‘CAT operators’ prevention of aircrew misuse of psychoactive substances’: The stakeholders requested revalidation and verification of the costs related to the psychological assessment of pilots before commencing line flying, the costs for training people to carry out screening test at the operators, etc. These costs have been revised to reflect the market levels. In addition, the population of the tested people was expanded by integrating other safety-sensitive personnel (maintenance personnel).
- Methodology regarding the comparison of the overall economic impact (comparing the costs of the policy option against the turnover of the operator): The stakeholders suggested that the costs be compared against the employee cost for an operator and not against the total turnover. EASA does not agree with the suggestion because the applied standard methodology reflects how these costs impact on the business of the operator.
- Option which introduced a psychological assessment in the pre-employment selection process. This option has been contested by the stakeholders who claimed that no sufficient data<sup>23</sup> exists to support that the addition of psychological testing to the hiring process or to the routine medical examinations enhance the ability to assess the mental fitness of the pilot workforce. In response, EASA clarifies that the Opinion proposes a psychological assessment to ensure suitability for the job. It is already best practice and follows the IATA Guidance Material<sup>24</sup>. The revised proposal includes a provision to ensure that small operators with very low turnover of pilots and a small overall pilot workforce would not be required to conduct a psychological assessment.

Overall, the comments on the RIA led to changes in assessing the policy options and better justifying/clarifying/assessing the impacts of the different options and overall conclusions. The major controversial issues highlighted in the consultation process (e.g. conducting alcohol testing as part of the ramp inspection programme, mandating drug and alcohol testing by CAT operators) were re-analysed. In the current version of the RIA, they are specified as separate options in order to reassess their impacts separately (potential costs and benefits) on the different stakeholders and to distinguish their impact having also in mind the non-controversial issues/minimum changes in the Regulation.

<sup>22</sup> SERA.2020, transposing ICAO Annex 2, paragraph 2.5, into Commission Regulation (EU) No 923/2012 of 26 September 2012 to address the risks associated with the problematic use of psychoactive substances by safety-sensitive personnel.

<sup>23</sup> FAA study ([http://www.faa.gov/regulations\\_policies/rulemaking/committees/documents/media/Pilot%20Fitness%20ARC%20Report.11302015.pdf](http://www.faa.gov/regulations_policies/rulemaking/committees/documents/media/Pilot%20Fitness%20ARC%20Report.11302015.pdf))

<sup>24</sup> IATA Guidance Material and Best Practices for Pilot Aptitude Testing (<https://www.iata.org/publications/Documents/pilot-aptitude-testing-guide.pdf>)



### 3.6. Policy options

In the identification of the policy options, the RIA analysed how the Task Force recommendations might be achieved in a holistic way, by integrating the possible solutions. The aim is to build robust, safety-driven and cost-efficient regulatory proposals which in combination will attain a much higher synergistic effect than stand-alone actions.

**Table 2 — Policy options**

<b>Option</b>	<b>Short title</b>	<b>Description</b>
0	No policy change	Baseline option (no change to the existing Air OPS rules). CAT.GEN.MPA.100 stipulates that a crew member shall not perform duties on an aircraft when under the influence of psychoactive substances or alcohol. Some Member States and operators already conduct random testing.
1	Minimum changes (Psychological assessment of flight crew and development of support programmes by CAT operators, as well as systematic D&A testing in specific cases)	<p>This option mandates:</p> <ul style="list-style-type: none"> <li>(a) psychological assessment of flight crew before commencing line-flying with CAT operators (Recommendation No 2 of the Task Force report and</li> <li>(b) access to a support programme for flight crew members (Recommendation No 6 of the Task Force report; and</li> <li>(c) systematic D&amp;A testing of air crew in specific cases (upon employment by an airline; post-incident/post-accident; with due cause, e.g. following reasonable suspicion), performed by CAT operators (Recommendation No 3 of the Task Force report).</li> </ul> <p>These changes are considered as minimum to achieve the objective of task and address the issues. Therefore, they are used as a basis for developing the other policy options. Consequently, all options afterwards are conceived integrating Option 1. This ensures that the minimum changes will be pursued regardless of the final preferred policy option.</p>
2	Random testing of flight crew by CAT operators in addition to the minimum changes through Option 1	<p>A CAT operator is requested to conduct random alcohol and drug screening &amp; testing on flight and cabin crew in addition to the minimum changes introduced through Option 1.</p> <p>This means that the CAT operator has to employ trained staff to carry out screening and testing. No testing method is prescribed. After a positive test result, blood testing is required. Confirmation of positive screening results will most likely be conducted on behalf of the operator by an independent laboratory. Confirmed positives need to be reported to the NAA. No quotas for random testing are foreseen as they depend on the operator's risk assessment. Next to personnel required to conduct the screening, additional policies and procedures, as well as facilities are necessary.</p>



Option	Short title	Description
3	Alcohol screening of flight and cabin crew within the ramp inspection programme in addition to the minimum changes through Option 1	<p>This option envisages alcohol testing of flight and cabin crew. This testing is either conducted by ramp inspectors within the ramp inspection programme or by the competent law enforcement bodies authorised officials.</p> <p>In case the testing is conducted within the ramp inspection programme, the sampling rate will be established via the ramp inspection programme under the technical coordination of EASA and will be risk-based. It will take into account that random testing programmes already exist in some EASA Member States, where alcohol tests are conducted by the police or other State officials. Tests would be conducted via a non-invasive testing method, e.g. a breath analyser test. This option applies to EU operators, as well as third-country operators, since both EU and third-country operators are under the scope of ramp inspections.</p> <p>There are two possibilities depending on the national legal framework regarding who conducts the alcohol testing.</p> <p>(a) The test is conducted within the ramp inspection programme by ramp inspectors.</p> <p>(b) The test is conducted by the national law enforcement bodies, e.g. national police.</p> <p>In both cases, the result of the test (positive or negative) is included into the ramp database.</p>
4	Unannounced testing of flight crew after rehabilitation and return to work either within a support programme or by the operator in addition to the minimum changes through Option 1	This option envisages unannounced testing following rehabilitation and return to work in addition to the minimum changes introduced through Option 1.

**In practice, all Options 2 to 4 are built upon Option 1 (minimum changes). In the impact analysis, Options 2 to 4 are analysed separately from Option 1 as stand-alone options. This approach ensures clearer identification of the individual merits and shortcomings of each option. Afterwards, in the final assessment, they are combined to get an overview of the final results.**



**Discarded option:**

One of the initial options to not only test alcohol, but also drugs within the scope of the ramp inspection programme was discarded. Drug testing was discarded at the initial review as not being technically feasible, because of the following reasons:

- Drug testing is not suitable for ramp tests, because oral fluid screening cannot always be done in a few minutes. In some cases, oral fluid screening can take up to 20 minutes in case the mouth has to be washed because of contamination or because the person has a dry mouth syndrome. Oral fluid testing requires some protection of the person testing due to possible contact with bodily fluids.
- There is a higher number of false positives for drug testing in comparison with alcohol testing.

**3.7. Methodology****3.7.1. Data collection**

This RIA is performed based on several sources:

- Analysis of the impacts on random drug and alcohol testing, produced by Dr Ries Simons, consultant Aerospace Medicine (March 2016)

The above-mentioned independent consultant has produced and submitted to EASA an exhaustive overview of the advantages and disadvantages of random D&A testing, together with an option on whether random D&A testing should be made mandatory or whether other means, such as safety promotion material, are needed.

- Survey of national coordinators for the ramp inspection programme through an EU survey tool (<https://ec.europa.eu/eusurvey/runner/Survey-alcoholtesting-2016>) (April–May 2016)

The survey with regard to the proposal to integrate random alcohol testing within the ramp inspection programme, performed in accordance with ARO.RAMP of the Air OPS Regulation was sent to the ramp national coordinators.

In total, 21 ramp national coordinators from different EASA Member States participated in the survey. According to the survey results conducted between April and May 2016, in many Member States (11 out of 21), there seems to be no conflict with the national rules, as regards a joint ramp inspection with a national law enforcement agency. Only in a few EASA Member States national ramp inspectors could be entitled to conduct random alcohol tests during a ramp inspection. In many EASA Member States, there is a conflict with national rules as regards the extension of the privileges of the ramp inspector to plan and carry out random alcohol testing. In other Member States, it is considered less feasible to have a joint ramp inspection with a national law enforcement agency due to:

- the police currently not being authorised by law to conduct alcohol testing on the ramp;
- rules and procedures of ramp inspectors and police not aligned;
- mixing the jurisdiction of the police and ramp inspections;





- unwillingness of the police to take part in such tests due to lack of resources;
- long procedures (It takes time until the law enforcement crew arrives at the scene, upon a call by the ramp inspectors' team. This would lead to delaying the aircraft and if it is proved that one of the pilots has a confirmed positive test, then it should lead to grounding the aircraft); and
- random alcohol testing by police, in aviation as well as other transport modes, is only allowed by order of the State Prosecutor.

Overall, it is suggested that either the ramp inspectors' privileges are extended to conduct the random alcohol screening during a ramp inspection, or the random test is conducted by national law enforcement agencies in accordance with national laws<sup>25</sup>. The results are integrated into the present RIA. It should be noted that many of the respondents shared the opinion that the time for response was considered to be too short to provide a detailed, comprehensive overview, considering that coordination with other services was necessary. The results of the survey, including data received on the economic impact, have been included into this RIA.

- Questions sent to some specific operators, who already conduct random D&A testing

Questions on alcohol and drug policy of CAT operators, as well as costs of such a policy were sent to several European operators in the beginning of May 2016. Input was only received from two operators and the scarce data received, including on the economic impact, have been included into this RIA.

- Feedback by stakeholders from the Aircrew EASA Action Plan Conference which was held on 15–16 June 2016<sup>26</sup>

Preliminary results of this RIA were presented to the conference and feedback from the stakeholders was collected. In the conference, a strong support has been given to the random testing as a follow-up of pilot support programmes.

- Comments and suggestions during the consultation of the draft Opinions and Decisions.

Proposals and comments on the RIA were taken into account and better analysis of the overall impacts of the policy options was carried out.

### 3.7.2. Applied methodology in comparing options

The methodology applied for this RIA is the multi-criteria analysis (MCA), which allows comparing all options by scoring them against a set of criteria: safety, economic and social impacts. MCA covers a wide

<sup>25</sup> The results of the survey as regards who shall be in charge of conducting alcohol random testing are as follows: 7 Member States out of 21 suggest that this should be performed by police, as it is the current practice; 2 Member States agree that the ramp inspectors' privileges might be extended to include alcohol screening and the testing results are included into the ramp database; 4 Member States agree that whenever national law enforcement agencies conduct random alcohol screening, a joint ramp inspection with a national law enforcement agency might be carried out; 1 Member State proposes that it should be a CAT operator's task and 7 Member States do not express preferences.

<sup>26</sup> <http://www.easa.europa.eu/easa-and-you/aircrew-and-medical/follow-up-germanwings-flight-9525-accident>



range of techniques that aim at combining a range of positive and negative impacts into a single framework to allow easier comparison of scenarios.

The scoring of the impacts uses a scale of – 5 to + 5 to indicate the negative and positive impacts of each option (i.e. from ‘very low’ to ‘very high’ negative/positive impacts). Intermediate levels of benefits are termed ‘low’, ‘medium’ and ‘high’ to provide for a total of five levels in each one of the positive and negative directions, with also a ‘no impact’ score possible.

**Table 3 — Scale with scoring of the impacts**

Positive impact	Score	Negative impact	Score
+ 5	Very high positive impact	– 5	Very high negative impact
+ 4	High positive impact	– 4	High negative impact
+ 3	Medium positive impact	– 3	Medium negative impact
+ 2	Low positive impact	– 2	Low negative impact
+ 1	Very low positive impact	– 1	Very low negative impact
0	Insignificant	—	—

Every option is analysed as a stand-alone option and the scores are attributed individually to Options 1, 2, 3, and 4 without considering that Option 1 is by default already integrated into Options 2, 3 and 4. Nevertheless, at the end of the analysis when a comparison of all options is made, the final scores for Option 2, 3, and 4 integrate the results of their individual assessment plus adding the scores for Option 1. This approach achieves a threefold objective:

- Every option is analysed and assessed in terms of its own merits and shortcomings. Thus, every option is attributed with individual score.
- The final comparison is made based on the summing up of the scores from Option 1 and Option 2 (Option 1 + Option 2), scores from Option 1 and Option 3 (Option 1 + Option 3) and Option 1 and Option 4 (Option 1+ Option 4). The comparison is made in a separate table in the conclusion. It is assumed that the cumulative impacts of Option 1 and every consecutive option (Option 2, 3 and 4) is measured by the summing up of the individual scores of each option.
- The final outcome of the comparison defines the best combined options, considering a benchmark above the score of Option 1, e.g. every combination of options higher than Option 1 (minimum changes) might trigger a synergistic effect preventing the misuse of psychoactive substances and alcohol and promoting the safe exercise of the flight crew privileges.



3.8. Analysis of impacts on the affected stakeholders

3.8.1. Safety impact

Table 4 — Safety impact

Option	Safety impact	How are the stakeholders affected (level of impact)?			
		Operators	Aircrew	NAA's	EASA
Option 0 No policy change	Medium negative impact.	Each stakeholder continues to be exposed to the safety risks stemming from the current situation.			
Option 1 Minimum changes (psychological assessment, systematic D&A testing & support programme)	Medium positive safety impact. CAT operators will be required to: <ul style="list-style-type: none"> <li>— conduct a psychological assessment of flight crew before commencing line flying;</li> <li>— prevent aircrew misuse of psychoactive substances via systematic D&amp;A testing; and</li> <li>— enable access to a support programme for flight crew.</li> </ul>	<b>Medium positive</b>	<b>Low positive</b>	<b>Low positive</b>	<b>Very low positive</b>
Option 2 Random testing of crew by CAT operator	High positive impact. The safety impact will be positively affected due to the deterrent effect on the decision to misuse alcohol and drugs. The whole population of the flight crew will be part of the test and, in terms of absolute number of pilots, it is expected that there will be a high number of tested persons as compared to Option 3. This option has already been in place in some	<b>High positive</b>	<b>High positive</b>	<b>Low positive</b> NAA could revoke the licence of flight crew with confirmed positive	<b>Very low positive</b> EASA will only receive information from Standardisation inspections of



Option	Safety impact	How are the stakeholders affected (level of impact)?			
		Operators	Aircrew	NAA's	EASA
Option 3 Alcohol screening of crew members either by law enforcement bodies or within the scope of the ramp inspection programme	<p>operators and other countries like the USA.</p> <p>High positive safety impact due to a proactive deterrent effect on the decision to misuse psychoactive substances<sup>27</sup>. In addition, high positive impact as it would also apply to third-country operators.</p> <p>Random alcohol testing has a minimal selection bias and uses an objective method which positively contributes to safety. Despite a very low yield (0.091%)<sup>28</sup> and a very small testing window of maximum 8 hours, safety will be influenced positively, due to the deterrent effect, and because ramp inspection checks apply also to third-country operators, not only to EU operators. The sampling rate will depend on a risk assessment of the authority<sup>29</sup>. EASA will ensure technical coordination to specify appropriate sampling rates. A risk-based alcohol testing programme should take into account recognised information on safety aspects with regard to third-country operators and EU operators, such as</p>	<b>High positive</b>	<b>High positive</b>	<p>results.</p> <p><b>Medium positive</b></p> <p>NAA could revoke the licence of flight crew with confirmed positive results.</p>	<p>NAA's</p> <p><b>Medium positive</b></p> <p>The ramp database will include data on confirmed positive tests.</p>

<sup>27</sup> ICAO, 1995

<sup>28</sup> In 2013, the random alcohol test violation rate was 0.091 % according to FAA data. The rate for the pilots is 0.044%.

<sup>29</sup> According to the Eurocontrol data, EU and third-country operators (scheduled and non-scheduled CAT, as well as IFR GA) perform some 3.8 million flights to EASA Member States. The current inspection rate is around 0,275 % of all flights. Assuming that 10 % of ramp inspections include alcohol testing, we assume approximately 60 ramp inspections per year per NAA where alcohol test will be carried out.



Option	Safety impact	How are the stakeholders affected (level of impact)?			
		Operators	Aircrew	NAAs	EASA
Option 4 Unannounced testing of flight crew after rehabilitation and return to work either within a support programme or by the operator	<p>information on whether the crew member is already subject to a robust random alcohol testing programme under a State programme and information on the applicable sampling rate of such a State programme. It has a high safety impact also because it would be focused on flight and cabin crew members of operators who are not submitted to an operator random testing programme.</p> <p>Medium positive safety impact. Data over the last 40 years on rehabilitation and testing procedures either as part of a support programme or by the operator have shown that testing of pilots, who have returned to work, is a very effective mitigating measure with high safety benefits. This testing is a valuable tool in the context of alcohol and drug treatment and rehabilitation programmes. In such programmes, testing will be implemented when an individual has been treated for problematic use/misuse of alcohol or drugs. There is convincing evidence<sup>30</sup> that this form of testing is essential to maintain this person’s abstinence from alcohol or drugs, thus contributing to improving safety.</p>	<b>Medium positive</b>	<b>Very high positive</b>	<b>Low positive</b> NAA could revoke the licence of flight crew with confirmed positive results.	<b>Very low positive</b> EASA will only receive information from Standardisation inspections of NAAs

<sup>30</sup> Li et al. 2007



Using MCA and based on the analysis above, the safety impact assessment is visualised as follows:

**Table 5 – Safety impacts per option**

Criteria	Option 0 No policy change	Option 1 Minimum changes	Option 2 Random testing of flight crew by CAT	Option 3 Alcohol screening of flight crew during ramp inspections	Option 4 Unannounced testing of flight crew after rehabilitation.
Safety impact	-3	+3	+4	+4	+3

Conclusion regarding safety impact

Currently, **Option 0 induces medium negative impact**. On the contrary, the proposed options vary in terms of the degree of improvement as regards the current situation.

**Option 1 has a medium positive safety impact**, because it would mandate some changes to improve the safety (conduct a psychological assessment of flight crew before commencing line flying; prevent aircrew misuse of psychoactive substances; and enable access to a support programme for air crew, systematic D&A testing before employment, after accident/incident, with due cause).

**Option 2 has a high positive safety impact**, because it will be applied to the whole population of the flight crew, will be part of the test, and, in terms of absolute number of pilots, it is expected that there will be a high number of tested persons.

**Option 3 has also high positive safety impact**, because the deterrent effect of random testing during ramp inspections does not only apply to flight crew of EU operators, but also to flight crew of third-country operators via the scope of ramp inspections. It has a high safety impact also because it would be focused on crew members of operators who are not submitted to an operator random testing programme. In addition, the data obtained can be assessed by EASA and regulators to develop future policy solutions.

**Option 4 has a medium safety impact**, because it ensures unannounced testing either as part of a support programme or by the operator and it is applicable to the small, but higher-risk, population of pilots who have returned to work after rehabilitation and who want to demonstrate that they can safely exercise their duties.



3.8.2. Social impact

Table 6 — Social impact

Option	Social impact	How are the stakeholders affected (level of influence)?			
		Operators	Aircrew	NAA's	EASA
Option 0 No policy change	Low negative social impact due to the social tension in society, operators, and the NAA. The society expects the regulatory bodies to take action.	Low negative social impact since the status quo is maintained			
Option 1 Minimum changes  (psychological assessment, systematic D&A testing & support programme)	Medium positive social impact due to a safer working environment for the pilots and due to the introduction of support programmes.	<b>Medium positive</b>	<b>High positive</b>	<b>Not applicable</b>	<b>Not applicable</b>
Option 2 Random testing of flight crew by CAT operator	The impact on the organisation of the work of the operator will be medium negative.  The sample collection and testing process should be designed to ensure that the result is reliable. Confirmation of a positive first result	<b>Medium negative</b>  In terms of organisation, the CAT operator needs to amend its procedures and policies.	<b>Medium negative</b>  High rate of false positive drug tests <sup>32</sup> will	<b>Non-significant impact</b>  NAA's will have to implement procedures to	<b>Non-significant impact</b>  Standardisation would have to verify compliance

<sup>32</sup> Random drug testing has significant false positive rates caused by the use of approved prescription and OTC medication, food (e.g. bread with poppy seed), environmental contamination (e.g. Tetrahydrocannabinol (THC)), and methodological limitations. A statistical principle is that in a population where the prevalence of psychoactive substance use is low, such as pilots, a highly sensitive test (such as most drug tests) will inevitably show significant false positive rates. Investigators found rates of false positive results including 22 % of opioids, 46 % methadone, 21 % amphetamines, 61 % benzodiazepines, 12 % cocaine, and 21 % marijuana identified as positive on point of care (POC) screening tests but negative on laboratory tests using LC-MS/MS (Liquid Chromatography-Mass Spectrometry) (ASAM, 2013).



Option	Social impact	How are the stakeholders affected (level of influence)?			
		Operators	Aircrew	NAA's	EASA
	<p>should be undertaken by an independent laboratory. A confirmed positive result should be reported to the relevant competent authority. Monitoring of results should be undertaken regularly and should be taken into account in order to determine future testing frequency. The D&amp;A testing policy should be communicated to affected staff.</p> <p>Any commercial pilot may refer themselves via their AME to a clinic if concerned they have an alcohol or drug problem. AMEs are trained by the NAA to support the operator in implementing a random D&amp;A policy. Results are shared with the competent authorities.</p> <p>In addition, feedback received from operator associations and pilot and cabin crew associations with regard to random testing has been highly critical, pointing to the legal framework that needs to be established and the many questions regarding a random testing policy. In accordance with the ICAO Manual, no type of testing is more controversial than random testing. The ICAO Manual also states that 'all types of testing raise the possibility of controversy in the workplace. In low prevalence populations, especially, alternative methods of early detection might be more acceptable, effective and less expensive'.</p>		<p>have negative social impact if the pilot needs to be grounded due to false positive result that has to be confirmed.</p>	<p>oversee the CAT operators' policies.</p>	<p>of operators via oversight visits.</p>





Option	Social impact	How are the stakeholders affected (level of influence)?			
		Operators	Aircrew	NAA's	EASA
	<p>As regards the pilots, there is another negative impact. Random controls would rather obstruct an open climate within a company and reduce the motivation of staff to seek help at an early stage. They would as well discourage the engagement of others to motivate colleagues for seeking treatment<sup>31</sup>. The random testing risks to undermine the effectiveness of support programmes and may hamper the trust.</p> <p>Apart from these effects, there is another marginal positive social impact. The employment will be marginally affected, because the CAT operator will be requested to employ trained staff to carry out screening and testing.</p>				
Option 3 Alcohol screening of crew members either by law enforcement bodies or within the scope of the ramp inspection	<p>The social impact is analysed with reference to the ramp inspectors, pilots and passengers. The overall impact is considered very low negative. The negative impact is due to the alcohol screening which, however, is considered very low, because the test would not be invasive. As regards the ramp inspectors, they would be trained to do the alcohol screening. No negative impacts on conducting the ramp check are expected. In</p>	<p><b>Very low negative</b></p> <p>In terms of the organisation of the work if the pilot needs to be grounded and a replacement has to be found<sup>33</sup>.</p>	<p><b>Very negative</b></p> <p>If a pilot needs to be grounded due to a positive result that will require a second confirmation</p>	<p><b>low negative</b></p> <p>The impact on the workforce of the ramp inspections is negatively affected, but not significantly because the NAA</p>	<p><b>Non-significant impact</b></p> <p>Amending the ramp database &amp; sharing of information</p>

<sup>31</sup> Büringer (2015)

<sup>33</sup> According to the New Zealand's study on breath and blood alcohol testing programmes, the false positive result test rate is 0.04 %.



Option	Social impact	How are the stakeholders affected (level of influence)?			
		Operators	Aircrew	NAA's	EASA
programme	addition, this option has a positive impact on the passengers being reassured about the safety of the flights.		test.	would have the discretionary power to plan/organise the screening. In addition, the ramp inspectors would be trained to do the screening and the procedure would be completed within the time limits of the ramp check.	
Option 4	Medium positive social impact.	<b>Medium positive</b>	<b>Very high positive</b>	<b>Non-significant impact</b>	<b>Non-significant impact</b>
Unannounced testing of flight crew after rehabilitation and return to work either within a support programme or by the operator	Pilot support programmes effectively encourage pilots to self-declare and they also increase reporting from fellow pilots, who might otherwise avoid reporting, due to fear of loss of licence of the affected pilot. In case a pilot denies to accept that they have an issue of misuse of psychoactive substances and do not voluntarily self-refer to the support programme, the possibility of testing a pilot at any time with due cause, e.g. following reasonable suspicion, provides a strong incentive for pilots who deny that they	Testing is a valuable tool in the context of alcohol and drug treatment and rehabilitation programmes.	Testing is a valuable tool in the context of alcohol and drug treatment and rehabilitation programmes.	NAA's will have to implement procedures to oversee operators' policies.	Standardisation inspections would have to verify compliance of operators via oversight visits.



Option	Social impact	How are the stakeholders affected (level of influence)?			
		Operators	Aircrew	NAA's	EASA
	<p>might have a problem, to self-refer.</p> <p>Pilot support programmes improve reporting rates from fellow pilots and effectively mitigate the risks of relapses if testing is part of a follow-up and is included as a condition in the support programme.</p> <p>Support programmes also ensure that pilots can access help at an early stage, where only a small amount of preventive measures and support can have a very positive impact.</p> <p>This option has a high positive social impact, because unannounced testing as part of a support programme after rehabilitation is widely supported by addiction specialists, operators and pilots. It also contributes to the increase of the public trust. However, it has the same consequences as Option 2 for the pilots if they need to be grounded due to a false positive result.</p>				

Using MCA and based on the analysis above, the social impact assessment is visualised as follows:

**Table 7 – Social impacts per option**

Criteria	Option 0 <i>No policy change</i>	Option 1 <i>Minimum changes</i>	Option 2 <i>Random testing of flight crew by CAT</i>	Option 3 <i>Alcohol screening of flight crew during ramp inspections</i>	Option 4 <i>Unannounced testing of flight crew after rehabilitation</i>
Social impact	-2	+3	-3	-1	+3



Conclusion regarding social impact

From the social aspect, **Option 0 has a low negative social impact**, because it would not address the social tension after the Germanwings accident which might even evolve negatively in the future.

**Option 1 has a medium positive social impact** due to the introduction of access to pilot support programmes and due to a safer working environment for the pilots.

**Option 2 has a medium negative social impact** due to the possibility of raising controversy in the workplace and a low prevalence in the air crew population.

**Option 3 might have a very low negative social impact**, because the NAAs would have the discretionary power to plan/organise the screening. In addition, the ramp inspectors would be trained to do the screening and the procedure would be completed within the time limits of the ramp check. In addition, this option might be more easily implemented, because in some Member States there already is a practice of national law enforcement agencies, which test flight crew on alcohol. However, in many Member States the coordination between the law enforcement agency and the ramp inspector will be difficult, due to different legal frameworks. As regard the pilots, there might be a negative impact in case of false positive test in which case the pilot needs to be grounded for a second confirmation test.

**Option 4 ensures a medium positive social impact**, because unannounced testing after rehabilitation is a valuable tool in the context of alcohol and drug treatment and rehabilitation programmes.



## 3.8.3. Economic impact

Table 8 — Economic impact

Option	What is the impact	How are the stakeholders affected (level of influence)?			
		Operators	Aircrew	NAAs	EASA
Option 0 No policy change	No impact.	Neutral economic impact since the status quo is maintained.			
Option 1 Minimum changes (psychological assessment, systematic D&A testing & support programme)	The overall economic impact is medium negative. It is estimated to be around 0.24 % of the operator's turnover (see Tables 9 and 10)	<b>Medium negative</b>	<b>Medium negative</b>	<b>Not applicable</b>	<b>Not applicable</b>
Option 2 Random testing of flight crew by the CAT operator	The overall impact is expected to be medium negative (see Table 11). The overall impact of the costs is estimated at 0,22 % of the operators' turnover.  This option is expected to test annually around 25 % <sup>34</sup> of flight and cabin crew. In the case of a medium-sized operator, this would mean around 1 300 flight and cabin crew <sup>35</sup> . The unit price for drug and alcohol test is around EUR 150 <sup>36</sup> per tested flight crew member (see Table 11).	<b>Medium negative</b>	<b>Medium negative</b>	<b>Non-significant</b> Oversight entails some costs in terms of trained inspectors and inspecting staff.	<b>Non-significant</b> The oversight scope would have to be extended and some costs are expected.

<sup>34</sup> Though there is no quotas for random testing and they depend on the operator's risk assessment, for the sake of the calculation, 25% of the air crew staff is suggested for random D&A testing. 25% is the minimum annual testing rate (and since 1998) set by the FAA for drug testing and 10% for alcohol testing.

<sup>35</sup> Medium size operator have around 1500 flight crew and 3700 cabin crew

<sup>36</sup> The unit price of EUR 150 is the determined cost for performing a combined random D&A testing on flight crews.



<p>Option 3 Alcohol screening of crew members either by law enforcement bodies or within the scope of the ramp inspection programme.</p>	<p>The overall impact is expected to be medium negative (see Table 12). The overall impact of the costs is estimated at 0,2–0.3 % of the NAA’s budget.</p> <p>Whenever the ramp inspector conducts the random test, the average workload of the ramp inspector to prepare, carry out and report on the results and follow-up on the findings is around 63 minutes per inspection in addition to their current workload (see Table 12). The overall cost for this sub-option is around EUR 96 000 per NAA (see Table 12).</p> <p>Whenever the national enforcement body conducts the random test, the average workload of the ramp inspector to prepare, carry out and report on the results and follow-up on the findings is around 54 minutes per inspection in addition to their current workload (see Table 12). The overall cost for this sub-option is around EUR 71 000 per NAA (see Table 12).</p>	<p><b>Medium negative</b></p> <p>In case of a confirmed positive test, the CAT operator needs to find a replacement.</p>	<p><b>Medium negative</b></p> <p>Covered in the operator cost impact.</p>	<p><b>Medium negative</b></p> <p>0.2-0.3 % of the NAA budget on average (see Table 12).</p>	<p><b>Non-significant</b></p> <p>Oversight scope would have to be extended and some costs are expected.</p>
<p>Option 4 Unannounced testing of flight crew after rehabilitation and return to work either within a support programme or by the operator</p>	<p>Support programmes are highly cost-efficient, with an average cost of less than EUR 1 per employed pilot who is involved in the support programmes per month<sup>37</sup> (RIA Appendix 2).</p> <p>The overall economic impact of a support programme is difficult to estimate and depends on the chosen programme, i.e. an in-house support programme or affiliation to an existing programme, whereby several operators join forces to establish a support programme. Both examples currently exist within EU operators. From data obtained from existing programmes, including the Human Intervention Motivation study (HIMs) programmes in Canada and the US, it is accepted that support programmes are the most cost-</p>	<p><b>Low negative</b></p> <p>Support programmes are highly cost-efficient.</p>	<p><b>Low negative</b></p> <p>Voluntary work as a peer might entail some very low negative economic impact.</p>	<p><b>Non-significant</b></p> <p>Oversight entails costs in terms of trained inspectors and inspecting staff.</p>	<p><b>Non-significant</b></p> <p>The standardisation of inspection scope would have to be extended and some costs are expected.</p>

<sup>37</sup> Data from Stiftung Mayday, presented during the Aircrew EASA Action Plan Conference, 15–16 June 2016



efficient and economic way of ensuring that pilots, who misuse psychoactive substances are treated and return to work within a reasonable time frame. The economic benefit is directly translated into maintaining the pilot inside the workforce, which is demonstrated by a 97 % success rate in the case of e.g. the Canadian HIMs Project.



Table 9 — Total number of screened flight crew considered in Option 1<sup>38</sup>

<i>Total number of screened flight crew for psychological assessment before commencing line flying</i>	<b>100</b>	<i>Total number of screened flight crew, cabin crew, and other safety-sensitive personnel for D&amp;A testing in specific cases</i>	<b>1 500</b>
Number of flight crew newly recruited per year/operator	100	Number of newly recruited (flight crew — 100 people, cabin crew — 500 people, other safety-sensitive personnel — 900 people) per year/operator	1 500
Number of screened pilots in due cases per year/operator	negligible	Number of screened pilots in due cases per year/operator	negligible
Number of flight crew/cabin crew in the follow-up of support programmes per year/operator	negligible	Number of flight crew/cabin crew in the follow-up of support programmes per year/operator	negligible

Table 10 — Costs for a CAT operator to implement Option 1

<b>Costs for operator</b>		<b>Drug and alcohol testing performed by CAT operators in specific cases (upon employment by an airline; post-incident/post-accident; with due cause, e.g. following reasonable suspicion)</b>	
<b>Psychological assessment of pilots before commencing line flying</b>			
Test establishment (fixed cost)	EUR 48 000	Labour costs for staff trained to carry out screening test (2 persons)	EUR 120 000
Carrying out test (for medium-sized operator with employed flight crew of 100 per year)	EUR 17 500	Screening per person for drugs and alcohol upon employment, after a serious incident or accident, with due cause and as part of a follow-up (for a medium-sized operator with 1 500 tested persons)	EUR 225 000
<b>Total for psychological assessment applies to pilots before commencing line flying</b>	<b>EUR 65 500</b>	Pre-selection alcohol-testers (EUR 650 each, 60 testers are sufficient for 1 500 tested persons)	EUR 39 000
		Purchase of drug tests (EUR 30 each for 60 testers which are sufficient for 1 500 tested persons)	EUR 1 800

<sup>38</sup> Data is based on historical analysis of the newly recruited flight crew, cabin crew and other safety-sensitive personnel in operators for 2012–2014.





	Confirmation test (0.5 % yield rate for drug testing <sup>39</sup> ) for alcohol and drug testing (1 000 EUR per test)	EUR 7 500
	<b>Total for drug and alcohol testing in specific cases</b>	<b>EUR 393 300</b>
Total costs for Option 1 per operator		<b>EUR 458 800</b>
Total number of operators in EASA Member States <sup>40</sup>		787
Total estimated costs for all operators		EUR 361 075 600
Airlines turnover at EASA Member State level		EUR 150 000 000 000
% of the costs as regards the turnover of CAT operators <sup>41</sup>		<b>0.24 %</b>

**Table 11 — Estimated costs for a CAT operator to implement Option 2<sup>42</sup>**

Estimated cost for random testing	Amount (EUR)
<i>One-off costs</i>	
Purchase of 20 breath analysers at EUR 650 each	13 000
Purchase of 20 drug testing equipment (saliva) at EUR 3 250 each	65 000
<i>Recurrent costs</i>	
Costs of the operators for labour costs for staff for random testing (average of 2 persons of trained staff who carry out screening tests usually by mouth swab, breath, blood, hair or urine sample)	120 000
Recurrent cost of random screening per person for drugs and alcohol of 25 % of staff <sup>43</sup> (for a medium-sized operator with a staff of 1 500 flight crew and 3 700 cabin crew). According to information received from operators, the unit price for drug and alcohol test is around EUR 150 <sup>44</sup> per tested crew member.	195 000
<i>Recurrent costs for confirmation testing by an independent laboratory</i>	
Confirmation test (assuming a 0.5 % yield rate <sup>45</sup> for random drug testing) (EUR 1 000 per test)	6 500
Confirmation test (assuming a 0.091 % yield rate <sup>46</sup> for random alcohol testing) (EUR 1 000 per test)	1 183

<sup>39</sup> For drug testing, the yield from 2006 to 2014 for annual random drug test positive rate was 0.524 % in the FAA programme.

<sup>40</sup> EASA Standardisation database 2015

<sup>41</sup> RIA Appendix 1 — Definition for the economic scale

<sup>42</sup> The data has been retrieved from the responses to the questionnaire sent to operators in May 2016.

<sup>43</sup> For the sake of the calculation, 25 % of the aircrew staff is suggested for random D&A testing. 25 % is the minimum annual testing rate (and since 1998) set by the FAA for drug testing and 10 % for alcohol testing.

<sup>44</sup> The unit price of EUR 150 is the determined cost for performing a combined random D&A testing on flight crews.

<sup>45</sup> For drug testing, the yield from 2006 to 2014 for annual random drug test positive rate was 0.524 % in the FAA programme.

<sup>46</sup> In 2013, the random alcohol test violation rate was 0.091 %.



<b>Total cost for Option 2 per operator</b>	<b>EUR 400 683</b>
Total number of operators in EASA Member States <sup>47</sup>	787
Total estimated costs for all operators	<b>315 337 521</b>
Airlines turnover at EASA Member State level	<b>150 000 000 000</b>
% of the costs as regards the turnover of CAT operators <sup>48</sup>	<b>0.21 %</b>

Table 12 — Estimated costs and workload per NAA to implement Option 3<sup>49</sup>

Item	Ramp inspector conducts alcohol screening	Law enforcement officer conducts alcohol screening & the results are included into the ramp database
<b>Average (additional) workload for each ramp inspector to do an alcohol testing (hours)</b>	1.05	0.9
<b>% of ramp inspectors requesting training on alcohol testing</b>	100 %	60 %
Initial costs		
<b>Training cost for ramp inspector (EUR) (average)</b>	850	140
<i>overall training costs for training for NAA (assuming an average of 10 ramp inspectors) (EUR)</i>	8 500	840
<b>Other one-off costs for ramp inspector to do alcohol testing (average)</b>		
<b>one-off cost for purchase of pre-selection alcohol-testers (10 testers for EUR 650 each) (average)</b>	6 500	0
Recurrent costs		
<b>— writing of protocols and coordination meetings with security forces responsible per year for all inspections) (60 ramp inspections per year<sup>50</sup>; between 9 and 10 hours for writing the protocols per inspection; EUR 120/man hour)</b>	75 600	64 800
<b>— calibration and service of the equipment</b>	5 000	5 000
<b>—alcohol analyser (only in case of a positive result) (EUR 7 500 unit price of one test that is paid for indicatively 0.1 person that has a positive result (60 inspections with a yield of 0.091 % for alcohol testing)</b>	410	410
<i>overall recurrent costs (per NAA) (EUR)</i>	81 010	70 210
<b>Overall estimated costs for alcohol testing per NAA</b>	<b>96 010</b>	<b>71 050</b>

<sup>47</sup> EASA Standardisation database 2015

<sup>48</sup> RIA Appendix 1 — Definition for the economic scale

<sup>49</sup> The data has been retrieved from the results of a survey to ramp national coordinators, May 2016

<sup>50</sup> According to the Eurocontrol data, EU and third-country operators (scheduled and non-scheduled CAT, as well as IFR GA) perform some 3.8 million flights to EASA Member States. The current inspection rate is around 0,275 % of all flights. Assuming that 10 % of ramp inspections include alcohol testing, we assume approximately 60 ramp inspections per year per NAA where alcohol test will be done.



Total number of NAAs in EASA Member States	31	
Total estimated costs for all NAAs	2 976 295	2 202 535
NAA budget at EASA Member State level <sup>51</sup>	1 000 000 000	
Impact of the estimated costs as regards the NAA budget	<b>0.30 %</b>	<b>0.22 %</b>

Using MCA and based on the analysis above, the economic impact assessment is visualised as follows:

**Table 13 — Economic impacts per option**

Criteria	Option 0 <i>No policy change</i>	Option 1 <i>Minimum changes</i>	Option 2 <i>Random testing of flight crew by CAT operator</i>	Option 3 <i>Alcohol screening of flight crew during ramp inspections</i>	Option 4 <i>Unannounced testing of flight crew after rehabilitation</i>
Economic impact	0	-3	-3	-3	-2

*Conclusion regarding the economic impact*

**Option 0 has no economic impact.**

**Option 1 has a medium negative economic impact**, inducing costs for operators around 0.24 % of their turnover.

**Option 2 has a medium negative economic impact**, with the overall impact of the costs estimated at 0,22 % of the operators' turnover.

**Option 3 has a medium negative economic impact** with incurred costs for the competent authorities around 0.2–0.3 % of an NAA's budget.

**Option 4 has a low negative impact.** Support programmes are highly cost-efficient, with a success rate of approximately 90 %, enabling pilots to return to flying duties within a reasonable time frame.

### 3.9. Conclusion

As mentioned in the methodology section (1.7.), every option is analysed and assessed in terms of its own merits and shortcomings. Thus, every option is attributed with an individual score (see Table 14).

**Table 14 — Assessment of individual options**

Criteria	Option 0 <i>No policy change</i>	Option 1 <i>Minimum changes</i> <i>(psychological assessment, systematic D&amp;A testing &amp; support programme)</i>	Option 2 <i>Random testing of flight crew by CAT operator</i>	Option 3 <i>Alcohol screening of flight crew during ramp inspections</i>	Option 4 <i>Unannounced testing of flight crew within after rehabilitation</i>
<b>Safety</b>	-3	+3	+4	+4	+3

<sup>51</sup> RIA Appendix 1 — Definition for the economic scale, indicative budget of NAAs at EASA Member State level



<b>Social</b>	-2	+3	-3	-1	+3
<b>Economic</b>	0	-3	-3	-3	-2
<b>Overall</b>	-5	+3	-2	0	+4

The final comparison is made based on the summing up of the scores of Option 1 and Option 2 (Option 1 + Option 2), the scores of Option 1 and Option 3 (Option 1 + Option 3), and the scores of Option 1 and Option 4 (Option 1 + Option 4). The comparison is made in a separate table in the conclusion. It is assumed that the cumulative impacts of Option 1 and of every consecutive option (Options 2, 3, and 4) are measured by the summing up of the individual scores of each option. The result is presented in Table 15.

The final outcome of the comparison defines the best combination of options, considering a benchmark above the score of Option 1, e.g. every combination of options higher than the Option 1 (minimum changes) might trigger a synergistic effect preventing the misuse of psychoactive substances and alcohol and promoting the safe exercise of the flight crew privileges.

**Table 15 — Final assessment and comparison of the policy options**

<b>Criteria</b>	<b>Option 0</b> <i>No policy change</i>	<b>Option 1</b> <i>Minimum changes (psychological assessment, systematic D&amp;A testing &amp; support programme)</i>	<b>Option 1 + Option 2</b> <i>Random testing of flight crew by CAT</i>	<b>Option 1 + Option 3</b> <i>Alcohol screening of flight crew during ramp inspections</i>	<b>Option 1 + Option 4</b> <i>Unannounced testing of flight crew after rehabilitation</i>
<b>Safety</b>	-3	+3	+7 (+3+4)	+7 (+3+4)	+6 (+3+3)
<b>Social</b>	-2	+3	0 (+3-3)	+2 (+3-1)	+6 (+3+3)
<b>Economic</b>	0	-3	-6 (-3 -3)	-6 (-3-3)	-5 (-3-2)
<b>Overall</b>	-5	+3	+1	+3	+7
<b>Selected option which is above the minimum changes, e.g. <math>\geq +3</math></b>	<b>NO</b>	<b>NO</b>	<b>NO</b>	<b>YES</b>	<b>YES</b>



The final result of the RIA demonstrates that a **combination of Option 1 (minimum changes), Option 3 (alcohol screening during ramp inspections) and Option 4 (unannounced D&A testing after rehabilitation)** contributes to maintaining a high level of aviation safety while providing a cost-efficient and socially acceptable framework. Therefore, the RIA recommends:

**(a) Mandating the minimum changes in the Air OPS Regulation as follows:**

- (1) Compulsory psychological assessment of flight crew — performed by CAT operators;
- (2) Requirement for CAT operators to enable access to a support programme for flight crew (compulsory); and
- (3) Systematic D&A testing in specific cases (upon employment by an airline; post-incident/post-accident; with due cause, e.g. following reasonable suspicion) — performed by CAT operators.

The expected **benefits** of these changes are:

- Medium positive safety impact on a CAT operator that will be required to:
  - conduct a psychological assessment of flight crew before commencing line flying;
  - prevent aircrew misuse of psychoactive substances; and
  - enable access to a support programme for flight crew.
- Safer working environment for the pilots, also due to the introduction of peer support groups within a support programme.
- Access of pilots to a support programme has been proposed with RMT.0700 as an effective mitigation measure to encourage self-declaration, and as a preventive measure, in line with the BEA report<sup>52</sup> and Recommendation No 6 of the Germanwings Task Force report published on 17 July 2015.

The expected drawback of these changes is:

- Incurred costs for CAT operators to apply the changes the impact of which is assessed as medium negative (0.24 % of the operators' turnover).

**(b) Random alcohol tests of flight and cabin crew either conducted within the ramp inspection programme or by the competent law enforcement bodies authorised officials.**

The expected **benefits** of random alcohol tests of flight and cabin crew, either conducted within the ramp inspection programme or by the competent law enforcement bodies authorised officials, are:

- Random alcohol tests apply not only to pilots and cabin crew from EU but also from third-country operators.
- In cases where ramp inspectors are not entitled to conduct alcohol tests, random alcohol tests can also be performed through cooperation between law enforcement agencies and ramp inspectors.

<sup>52</sup> Recommendation FRAN-2016-021 (BEA): EASA ensure that European operators promote the implementation of peer support groups to provide a process for pilots, their families and peers to report and discuss personal and mental health issues, with the assurance that information will be kept in-confidence in a just-culture work environment, and that pilots will be supported as well as guided with the aim of providing them with help, ensuring flight safety and allowing them to return to flying duties, where applicable.



- Results of random alcohol testing during ramp inspections will be included into the ramp database and the resulting data can be used for future evaluations and policy decisions.
- Showing zero tolerance for alcohol and drugs misuse from the regulator's perspective.

The expected **drawbacks** of random alcohol testing within the ramp inspection programme are:

- In some countries, this option might be difficult to implement. In order to mitigate the negative impact, it is suggested that a joint ramp inspection with a national law enforcement agency will be carried out, in cases where there is a conflict with national rules as regards the extension of the privileges of the ramp inspector to carry out random alcohol testing.
- It might have medium negative economic impact on the budget of the NAA. The impact of the random testing costs on the NAA budget is expected to be in the range of 0.2–0.3 % of their annual budget (EUR 71 000–96 000 per NAA).

### (c) Unannounced D&A testing after rehabilitation and return to work

The **benefits** of unannounced D&A testing after rehabilitation and return to work are as follows:

- Where the unannounced testing is performed under the management of a support programme, those support programmes are highly cost-efficient, with an average cost of less than EUR 1 per employed pilot who is involved in the support programme per month<sup>53</sup>.
- This option has a high positive safety impact, because pilot support programmes effectively encourage pilots to self-declare and it also increases reporting from fellow pilots, who might otherwise avoid reporting, due to fear of loss of licence<sup>54</sup> of the affected pilot.
- By ensuring access to a support programme, the operator allows feedback from peers and family within this programme.
- Support programmes that include unannounced testing after rehabilitation and return to work, have a proven success rate of over 90 %<sup>55</sup>, enabling pilots to return to flying duties within a reasonable time frame.
- In addition, data over the last 40 years on rehabilitation and testing procedures has shown that unannounced testing of pilots, who have returned to work, and who in some cases can be subject to testing for many months or years, is a very effective mitigating measure with high safety and social benefits.
- Pilot support programmes effectively mitigate the risks of relapses if random testing is part of a follow-up and is included as a condition in the support programme.
- Unannounced D&A testing after rehabilitation and return to work could be used as a tool to demonstrate sobriety for crew members, who have previously been identified misusing psychoactive substances.

<sup>53</sup> Data from Stiftung Mayday, presented during the Aircrew EASA Action Plan Conference, 15–16 June 2016.

<sup>54</sup> See recommendation of BEA report — FRAN-2016-014 (BEA): 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.

<sup>55</sup> Canadian HIMs Project



- Unannounced D&A testing after rehabilitation and return to work is supported by all stakeholders, including pilots themselves, who in most cases want to demonstrate that they are fit to fly.

The expected **drawbacks** of unannounced D&A testing after rehabilitation and return to work are:

- It has a limited range, e.g. a limited percentage of employees will be tested each year and only a few substances might be covered in the standard test procedures.
- Pilots who deny that they have a problem with misuse of psychoactive substances or another mental health problem might not want to admit that they have an issue and will not subscribe to the support programme and might never be tested. Even if their peers suggest them to participate in a support programme, they might not follow that suggestion, even if otherwise the operator can exercise the right to test with due cause, e.g. following a suspicion.
- If testing is performed within the support programme, it may discourage pilots, who do not want to submit themselves to unannounced testing, from joining



### 3.10. RIA appendices

#### RIA Appendix 1 — Definition for the economic scale

Geographic scope: EASA Member States

			EASA	NAA's	ATM / ANSP	Airlines
		Turnover (M€) 2012	140	1 000	8 000	150 000
<b>Qualitative description</b>	Score	Turnover impact	M€			
<b>Very high impact</b>	+/- 5	> +1.5%				
		]1 to 1.5 %[	2.10	15.0	150	2 500
<b>High impact</b>	+/- 4	]0.8 to 1 %[	1.40	10.0	90	1 500
		]0.6 to 0.8 %[	1.12	8.0	70	1 200
<b>Medium impact</b>	+/- 3	]0.4 to 0.6 %[	0.84	6.0	50	900
		]0.2 to 0.4 %[	0.56	4.0	30	600
<b>Low impact</b>	+/- 2	]0.1 to 0.2 %[	0.28	2.0	20	300
		]0.05 to 0.1 %[	0.14	1.0	10	150
<b>Very low impact</b>	+/- 1	]0.02 to 0.05 %[	0.07	0.5	5	75
		]0 to 0.02 %[	0.03	0.2	2	30
<b>No impact</b>	0		0.00	0.0	0	0

#### RIA Appendix 2 — Estimated costs of unannounced testing, if performed as part of a support programme or by the operator following rehabilitation and return to work<sup>56</sup>

Costs	Amount (€)	Savings	Amount (€)
Fix	145 000	Short-term sick leave	846 000
Training	100 500	Long-term sick leave	1 800 000
Personnel in training	147 000		
Supervision	90 000		
Total costs	482 500	Total savings	2 646 000
<b>Balance</b>	<b>2 163 500</b>		
<b>Cost per month and person potentially taken care of</b>	<b>&lt; 1</b>		

<sup>56</sup> Data from Stiftung Mayday, presented during Aircrew EASA Action Plan Conference, 15-16 June 2016





## RIA Appendix 3 — Economic impact on false positive test results

Criteria	Number per year
Flights potentially exposed to ramp inspection per year in the EASA Member States <sup>57</sup>	3 800 000
Ramp inspections (current ramp inspection rate is 0.275% of all flights)	$0,275\% * 3\ 800\ 000 = 10\ 450$
Number of ramp alcohol tests (10 % of ramp inspections include alcohol testing)	$10\ 450 * 10\% = 1\ 045$
Number of crew members tested (it is assumed that 4 crew: 2 flight crew and 2 cabin crew will be tested in one ramp inspection)	$4 * 1\ 045 = 4\ 180$
Number of crew staff with false positives result tests (0.04 % is the false positive rate) <sup>58</sup>	$0,04\ \% * 4\ 180 = 1.76$
Number of potential flights that will be affected by the crew with false positive alcohol test result <sup>59</sup>	2
Average cost for cancellation of a return long haul flight <sup>60</sup>	EUR 650 000
Total costs for replacement and delays fees per year	$EUR\ 2 * 650\ 000\ € = 1\ 300\ 000$
Airlines turnover at EASA Member State level <sup>61</sup>	150 000 000 000
Maximum financial burden on EU operators	$1\ 300\ 000 / 150\ 000\ 000\ 000 = 0.00001\ \%$
Overall assessment	Negligible impact

<sup>57</sup> According to the Eurocontrol data, EU and third-country operators (scheduled and non-scheduled CAT, as well as IFR GA) perform some 3.8 Million flights to EASA (28+3) Member States. The current inspection rate is around 0,275 % of all flights. Assuming that 10 % of ramp inspections include alcohol testing, we assume approximately 60 ramp inspections per year per NAA where alcohol test will be done.

<sup>58</sup> According to the New Zealand's study on breath and blood alcohol testing programmes, the false positive result test rate is 0.04 %.

<sup>59</sup> It is assumed that 1.76 persons with false positive rate refer to two different EU flights.

<sup>60</sup> The total cost of cancellation of return long haul flight, based on the stakeholder feedback received in the consultation process of the 'Draft Opinion and Decision' RMT.0700. It should be noted that the average cost for cancellation of a flight, according to Eurocontrol is estimated at EUR 114 500.

<sup>61</sup> RIA Appendix 1 — Definition for the economic scale



## RIA Appendix 4 — References

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## 4. References

### 4.1. Affected regulations

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).

### 4.2. Related decisions

- Decision 2014/025/R of the Executive Director of the European Aviation Safety Agency of 28 July 2014 adopting Acceptable Means of Compliance and Guidance Material to Part-ARO of 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 European Aviation Safety Agency of 24 April 2014 adopting Acceptable Means of Compliance and Guidance Material to Part-CAT of 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’

### 4.3. Reference documents

- Final Report of the Task Force on Measures Following the Accident of Germanwings Flight 9525 (<http://ec.europa.eu/transport/modes/air/news/doc/2015-07-17-germanwings-report/germanwings-task-force-final-report.pdf>)
- Action plan for the implementation of the Germanwings Task Force recommendations ([https://ec.europa.eu/transport/modes/air/news/2015-10-20-easa-action-plan\\_en](https://ec.europa.eu/transport/modes/air/news/2015-10-20-easa-action-plan_en))
- Final accident investigation report of the Bureau d’Enquêtes et d’Analyses pour la sécurité de l’aviation civile (BEA) ([https://www.bea.aero/uploads/tx\\_elyextendtnews/BEA2015-0125.en-LR\\_08.pdf](https://www.bea.aero/uploads/tx_elyextendtnews/BEA2015-0125.en-LR_08.pdf))
- IATA ‘Guidance Material and Best Practices for Pilot Aptitude Testing’, Effective March 2012, 2nd Edition (<https://www.iata.org/publications/Documents/pilot-aptitude-testing-guide.pdf>)
- ICAO Doc 9654 AN/945 ‘Manual on Prevention of Problematic Use of Substances in the Aviation Workplace’, First Edition — 1995
- ICAO Doc 8984 AN/895 ‘Manual of Civil Aviation Medicine’, Third Edition — 2012; Part I ‘LICENSING PRACTICES’, Chapter 2 ‘MEDICAL REQUIREMENTS’
- ICAO Doc 9859 AN/474 ‘Safety Management Manual (SMM)’, Third Edition — 2013
- ‘European Drug Report 2016: Trends and Developments’ by the European Monitoring Centre for Drugs and Drug Addiction, 2016 (<http://www.emcdda.europa.eu/system/files/publications/2637/TDAT16001ENN.pdf>)
- ‘European drug prevention quality standards’ by the European Monitoring Centre for Drugs and Drug Addiction, 2011 ([http://www.emcdda.europa.eu/system/files/publications/646/TD3111250ENC\\_318193.pdf](http://www.emcdda.europa.eu/system/files/publications/646/TD3111250ENC_318193.pdf))



## 5. Annex — EASA Germanwings Task Force recommendations<sup>62</sup>

1. The Task Force recommends that the **2-persons-in-the-cockpit recommendation** is maintained. Its benefits should be evaluated after one year. Operators should introduce appropriate supplemental measures including training for crew to ensure any associated risks are mitigated.
2. The Task Force recommends that all airline pilots should undergo **psychological evaluation** as part of training or before entering service. The airline shall verify that a satisfactory evaluation has been carried out. The psychological part of the initial and recurrent aeromedical assessment and the related training for aero-medical examiners should be strengthened. EASA will prepare guidance material for this purpose.
3. The Task Force recommends to mandate **drugs and alcohol testing** as part of a random programme of testing by the operator and at least in the following cases: initial Class 1 medical assessment or when employed by an airline, post-incident/accident, with due cause, and as part of follow-up after a positive test result.
4. The Task Force recommends the establishment of robust oversight programme over the **performance of aero-medical examiners** including the practical application of their knowledge. In addition, national authorities should strengthen the psychological and communication aspects of aero-medical examiners training and practice. Networks of aero-medical examiners should be created to foster peer support.
5. The Task Force recommends that national regulations ensure that an **appropriate balance is found between patient confidentiality and the protection of public safety.**

The Task Force recommends the creation of a **European aeromedical data repository** as a first step to facilitate the sharing of aeromedical information and tackle the issue of pilot non-declaration. EASA will lead the project to deliver the necessary software tool.

6. The Task Force recommends the implementation of **pilot support and reporting systems**, linked to the employer Safety Management System within the framework of a non-punitive work environment and without compromising Just Culture principles. Requirements should be adapted to different organisation sizes and maturity levels, and provide provisions that take into account the range of work arrangements and contract types.'

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<sup>62</sup> 'Action plan for the implementation of the Germanwings Task Force recommendations', Version 1 — 7 October 2015 ([http://easa.europa.eu/download/various/GW\\_actionplan\\_final.pdf](http://easa.europa.eu/download/various/GW_actionplan_final.pdf)).

