



Strengthening Aviation Safety in Europe

- Revision of EASA Regulation 1592/2002¹ -

1. Towards a One-Stop-Shop for Aviation Safety

To ensure high, uniform safety levels within the EU aviation market, the Commission proposes to revise the EASA Regulation 1592/2002. The proposal aims at closing some of the remaining gaps in Europe's safety architecture, by extending EASA's scope to Air Operations, Pilot Licensing and third-country aircraft, at strengthening the collective oversight and enforcement, and restructuring EASA's decision-making procedures.

The European Cockpit Association, representing over 34.800 pilots from 29 European countries, strongly welcomes these aims. They are a milestone towards EASA becoming the one-stop-shop for European aviation safety, quality, certification, rule-making and standardisation, guaranteeing a high level of aviation safety and uniform application of a single rule set. A single aviation market needs a single safety body.

The European Parliament, together with the Council of Ministers, is now called upon to further improve the Commission proposal and to focus it on those issues that directly contribute to a more systematic, reliable and uniform aviation safety system in Europe.

It is important that the financing problems EASA has faced in its *Certification* tasks do not distract from the ability to extend EASA's scope and to strengthen collective oversight. The budget problems are in the process of being addressed; they do not concern the Agency's *rule-making* tasks which are funded *publicly*. Financing issues should not be taken as a pretext for delaying the 1592 revision and its implementation.

Recent suggestions to co-finance EASA's budget by a passenger fee need careful examination. Collecting and administering such a fee might well cost more than the expected income for EASA. Also, such a fee would have EU passengers pay for the cost of certifying EU-made aircraft delivered to non-EU airlines (many of which are the EU's fiercest competitors on international routes). Hence, the disadvantages might well outweigh the intended advantages.

ECA herewith submits its position on the revision of Reg. 1592, as well as amendments that we urge MEPs to support – in the name of aviation safety in Europe.

2. Safety Can Not Wait – a Pragmatic Way Forward on “Governance”

The Commission proposal includes changes to the way EASA is governed – the so-called “governance”. They concern the Management Board's composition, its decision-making procedures, the creation of an Executive Board, as well as changes to the EASA Advisory Board where stakeholders are represented.

¹ Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1592/2002 of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency.

While these proposals aim at making the Agency's decision-making more efficient, they also affect the power-balance between Member States and the Commission, as well as among Member States. They have generated much controversy in the Council's Aviation Working Group and risk delaying the legislative process.

If they do, this would delay the introduction of those steps that will have a direct and immediate added value for aviation safety: EASA's scope extension and stronger safety oversight and enforcement mechanisms.

ECA strongly believes that the fatal accidents in recent years, the need for consumer confidence, as well as constantly increasing air traffic density in the European skies, do not allow for a delay in this crucial piece of safety legislation.

To avoid a delay of the extension of EASA's scope, ECA suggests that MEPs ask the Commission to come up with a new, separate proposal for the Agency's governance, and invites Parliament to revise the 1592 Regulation leaving the changes to the governance structure for a later stage.

3. Extension of EASA's Scope to Air Operations

When EASA was set up in 2002, the European co-legislators already envisaged the need for EASA to cover the safety aspects related to Air Operations ("OPS"). OPS are currently covered by the JAA (Joint Aviation Authorities) as well as by Annex III of the forthcoming EU-OPS Regulation. It is foreseen that Annex III will be repealed once EASA has the formal competence to deal with OPS issues.

To ensure the OPS rules are brought firmly into the Community framework and are applied uniformly across Member States, ECA strongly supports the Commission proposal to extend EASA's scope to Air Operations.

3.1. Transferring EU-OPS into EASA – in Line with Stockmann Report

Once its scope is extended, the Agency will be responsible for the operational issues covered by **MEP Ulrich Stockmann's** report on the EU-OPS Regulation, adopted on 5 July 2006 by the EP Plenary.

This concerns in particular Annex III of the EU-OPS Regulation, but also its **Article 8a**, upon which the EP had found a political compromise with the Council. It reads:

1. *By...* the European Aviation Safety Agency shall conclude a scientific and medical evaluation of the provisions of Subpart Q and, where relevant, of Subpart O of Annex III.*
2. *Without prejudice to Article 7 of Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, the European Aviation Safety Agency shall assist the Commission in the preparation of proposals for the modification of the applicable technical provisions of Subpart O and Subpart Q of Annex III.*

* Two years following the date of entry into force of this Regulation.

The EP strongly supported such a scientific/ medical evaluation, as well as the need for EASA to assist the Commission in making proposals to adapt Subpart O (Cabin Crew) and Subpart Q (Flight Time Limitations), based on the evaluation's findings.

As the 1592 proposal was published before the EP and Council found an agreement on the EU-OPS Regulation, the current 1592 proposal does not refer to the scientific evaluation and the EASA/Commission proposals on Subpart Q.

This needs to be corrected. Otherwise Art. 8a risks being lost once EASA has become responsible for OPS issues and EU-OPS Annex III is repealed. If not corrected, the EP would lose in the 1592 context what it achieved in the EU-OPS context.

ECA therefore suggests two amendments to mirror the provision of EU-OPS Art. 8a in the EASA 1592 Regulation.

<u>Commission Proposal</u> Art. 6(b)(6)	<u>Proposed ECA Amendment</u> Art. 6(b)(6)
	New third sub paragraph: <u><i>The implementing rules shall be developed, taking as a starting point the common technical requirements and administrative procedures specified in Annex III to Regulation (EC) No 3922/1991, as well as the provisions of Article 8a of that Regulation.</i></u>

This provision should be mirrored by a new **Recital** which reflects the content of Art. 8a:

<u>Commission Proposal</u>	<u>Proposed ECA Amendment</u> New Recital
	<u><i>When developing the implementing rules referred to in Article 6(b) paragraph 6, the Agency should take into account the results of the scientific and medical evaluation of the provisions of Subpart Q of Annex III to Regulation (EC) No 3922/1991. The Agency shall assist the Commission in the preparation of proposals for the modification of the applicable technical provisions of Subpart Q of Annex III to Regulation (EC) No 3922/1991, in line with Article 8a of that Regulation.</i></u>

3.2. Aircraft Inspections Before Each Flight

Annex IV of the proposed Regulation sets out the “Essential requirements” for Air Operations. This Annex is an important part of the new Regulation, setting the framework for air operations in Europe. ECA supports this Annex and, at this stage, has no further comments as to the text proposed.

However, the Council Working Group is in the process of watering down the important requirement to have an aircraft inspected – through pre-flight checks – before *each* flight, to determine if the plane is safe for operating (Annex IV, Art. 6.b). Council is expected to propose that such inspections do not need to be carried out before *each* flight, but – in case of a “consistent series of consecutive flights” – before such a *series* of flights.

From a safety point of view this is unacceptable. Checking before *each* flight is a standard procedure established by the aircraft manufacturers, in which a pre-flight inspection is set as an essential check. Safety is not assured after – or during – a series of flights when these inspections are not done, as some elements or equipment of the aircraft could be damaged from the previous flight and not being noticed, e.g.:

- Possible unreported damage to the aircraft by ground-staff (catering-, servicing-, luggage-carts, etc.)
- unnoticed bird-strike-damage (e.g. to the aircraft’s engine)
- Foreign Object Damage (“FOD”) due jet-blast on the empennage, engine and flight control surfaces
- Unmonitored access-doors, which remained unintentionally open.

From a passenger point of view, reducing the number of pre-flight checks would not help to build their confidence in air transport, nor in EASA as Europe’s central safety body.

Finally, after the recent security threats in London, the mandatory pre-flight security check before *each* flight becomes even more important, and should not be replaced by periodic checks after a series of flight.

ECA strongly recommends the EP *not* to follow the Council (preliminary) proposal to allow the number of pre-flight inspections to be reduced in case of a “consistent series of consecutive flights”.

4. Extension of EASA’s Scope to Pilot Licensing

When EASA was set up in 2002, the European co-legislators already envisaged the need for EASA to cover the safety aspects related to Flight Crew Licensing.

To ensure the JAA/EU-OPS rules are brought firmly into the Community framework and are applied uniformly across Member States, ECA strongly supports the proposal to extend EASA’s scope to Pilot Licensing, subject to some amendments.

4.1. Scientific & Technical Progress

Pilot Licensing needs to take into account the scientific and technical progress in aviation. Surprisingly, no such provision is contained in the 1592 proposal for the establishment of implementing rules (IR) related to Pilot Licensing (Art. 6 (a), para. 7).

This is probably a simple omission, as scientific and technical progress is mentioned in relation to IR for Air Operations (Art. 6(b), para. 6), airworthiness (Art. 5, para 5) and EASA opinions (Art. 14, para 2).

To align the licensing provisions with the other 1592 provisions and to ensure that scientific and technical progress are taken into account when IR are established, ECA proposes an insertion into Art. 6(a) para. 7.

<u>Commission Proposal</u> Art. 6(a), para. 7	<u>Proposed ECA Amendment</u> Art. 6(a), para. 7
<p>7. When establishing the implementing rules referred to in paragraph 6, the Commission will take specific care that they reflect the state of the art and the best practices in the field of pilots training, and that they allow for immediate reaction to established causes of accidents and serious incidents.</p>	<p>7. When establishing the implementing rules referred to in paragraph 6, the Commission will take specific care that they reflect the state of the art <u>and the, best practices, and scientific and technical progress</u> in the field of pilots training, and that they allow for immediate reaction to established causes of accidents and serious incidents.</p>

4.2. Medical Certificate for Pilots

The Commission proposes that a pilot shall be issued a medical certificate. This certificate may be issued – in the case of pilots involved in recreational operations – by a general medical practitioner (Art. 6(a), para. 2(3)).

However, a general medical practitioner without specific aero-medical training/experience does not have the qualification and knowledge to assess a pilot's medical condition with relation to an aeronautical certificate. He/she may know the applicant, but may not have access to the full medical background. Also, a general practitioner does not have the aero-medical background needed to evaluate the risk of a person flying an aircraft.² Only doctors with the appropriate training should be mandated to issue a certificate.

ECA therefore proposes to ***delete this provision.***

² It is for the same reasons that such a provision was not agreed upon in the JAA context.

<p align="center"><u>Commission Proposal</u></p> <p align="center">Art. 6(a), para. 2 (3)</p>	<p align="center"><u>Proposed ECA Amendment</u></p> <p align="center">Art. 6(a), para. 2 (3)</p>
<p>2(3). A pilot shall be issued a medical certificate when it is shown that he or she complies with the rules established to ensure compliance with the essential requirements governing medical fitness. This medical certificate shall be issued by aero medical examiners or aero medical centres; however, in the case of pilots involved in recreational operations, the certificate may be issued by a general medical practitioner.</p>	<p>2(3). A pilot shall be issued a medical certificate when it is shown that he or she complies with the rules established to ensure compliance with the essential requirements governing medical fitness. This medical certificate shall be issued by aero medical examiners or aero medical centres; however, in the case of pilots involved in recreational operations, the certificate may be issued by a general medical practitioner.</p>

4.3. Certificate for Flight Training Organisations

The Commission proposes that a person responsible for providing pilot training, or for assessing pilots' competence or medical fitness shall hold an appropriate certificate (Art. 6(a), para. 5).

Pilots involved in pilot training already hold a certificate by means of a *rating* inserted in their license, i.e. a note that states the privileges and the tasks the person is allowed to do. Requiring a new certificate would create double work, as current JAA regulation also requires a rating. ECA therefore proposes inserting a reference to the "rating".

<p align="center"><u>Commission Proposal</u></p> <p align="center">Art. 6(a), para. 5</p>	<p align="center"><u>Proposed ECA Amendment</u></p> <p align="center">Art. 6(a), para. 5</p>
<p>5. A person responsible for providing training for pilots, or for assessing their competence or medical fitness shall hold an appropriate certificate.</p>	<p>5. A person responsible for providing training for pilots, or for assessing their competence or medical fitness shall hold an appropriate certificate <u>or rating.</u></p>

4.4. Licence Issuing Bodies

The Commission proposes that a pilot licence can be issued by an Assessment Body, as long as it is for recreational flying (Article 6(a), para. 2 (2)).

ECA does not support that assessment bodies are entitled to issue pilot licences to recreational flying – unless such entitlement is conferred upon such bodies by way of delegation from national aviation authorities, as regulated by EU-wide legislation.

As some airspace is shared between recreational aircraft and other aircraft, the final responsibility for the issued licenses should still be in the remit of the national Civil Aviation Authorities, which in turn are audited by EASA and thus guarantee uniform application of common rules. If Assessment Bodies were allowed to issue licenses in their own remit, this could create a risk of diverging, incompatible standards.

ECA proposes to delete the provision on recreational licences being issued by Assessment Bodies.

<u>Commission Proposal</u> Article 6(a) para 2 (2)	<u>Proposed ECA Amendment</u> Article 6(a) para 2 (2)
<p>A pilot shall be issued a licence when it is shown that he or she complies with the rules established to ensure compliance with the essential requirements related to theoretical knowledge, practical skill and language proficiency. This licence may be issued by an assessment body when the privileges it confers are limited to recreational flying.</p>	<p>A pilot shall be issued a licence when it is shown that he or she complies with the rules established to ensure compliance with the essential requirements related to theoretical knowledge, practical skill and language proficiency. This licence may be issued by an assessment body when the privileges it confers are limited to recreational flying.</p>

4.5. Non-technical Skills – Risk of Arbitrary Decisions

Annex III of the proposed Regulation contains the “Essential requirements” for Pilot Licensing, setting the framework for pilot licensing in Europe. ECA supports this Annex and, at this stage, has no further comments as to the text proposed by the Commission.

However, the Council Working Group is in the process to add a new requirement for the skills to be demonstrated and maintained by a pilot: so-called “non-technical skills”, including the recognition and management of threats and errors.

Such non-technical skills include for example the ability to detect, fight, manage and solve certain errors, or how the person behaves in work groups/ teams. It is obvious that such skills are useful for every pilot. Any experienced pilot license holder does have such skills. However, to make the demonstration of these “soft” skills a prerequisite for obtaining or keeping a pilot license is not acceptable because:

- these skills are not clearly definable and hence open for arbitrary interpretation;
- they could be abused as a pretext to punish “unpopular” pilots;
- they are not scientifically proven, no objective methods are yet in place;
- there are no clearly defined trainer-competencies for such skills and checkable ‘watermarks’ ;
- the skills, their interpretation and assessment depend very much on the culture (i.e. dependent on the company and the nationality involved).

This is an issue that requires further investigation before including it in Annex III.

ECA strongly recommends to the EP not to follow the Council (preliminary) proposal to include non-technical skills in Annex III.

5. Extension of EASA's Scope to Third Country Aircraft

At least since the introduction of the “Black-lists” on unsafe foreign air operators, it has become clear that high safety standards also need to be observed by 3rd country operators who fly into Europe and their respective national oversight bodies.

Following the same logic, the Commission proposes to impose common rules on third-country aircraft operating in the EU, within the limits imposed by the Chicago Convention. Crucially, it proposes that foreign operators' compliance with the common rules have to be attested by a certificate or attestation.

ECA supports the initiative to impose common rules on third country aircraft, as it has distinct safety benefits. However, it is crucial that the EU's certification/attestation is compatible with ICAO and designed in a way that reduces the risk of “retaliation” by 3rd countries

To ensure this, the Commission proposal needs to be made more transparent and consistent. Currently, the relevant provisions are scattered all over the Regulation. ECA suggests to *regroup* those provisions in a single article.

The Council Aviation Working Group is in the process of developing such a new Article 6(c). This is a welcome initiative and – at this stage – it seems that Art. 6(c) contains the necessary safeguards against the risk of retaliation.

Although no AOC should be imposed to Operators engaged in non-commercial operations of complex motor-powered aircraft, they nevertheless shall comply with the same safety rules as the other participants. A declaration of their capability and means to discharge the responsibilities associated with the operation of the aircraft is considered not enough, since this kind of self-declaration is questionable, given the safety record of this type of operation

ECA recommends to the EP to regroup all 3rd country operator related provisions in a new, comprehensive article, based on the text currently being discussed in the Council Working Group. Non-commercial Operators of complex motor-powered aircraft should comply with all the requirements except the necessity of providing an AOC.

6. Strengthening Collective Oversight & Enforcement

The Commission proposes a strengthened Article obliging Member States and the Agency to cooperate through collection and sharing of information to ensure implementation of the Regulation. This new Article also includes ramp inspections of EU and foreign aircraft at airports, carried out by EASA (Art. 7 – Collective Oversight).

ECA strongly welcomes this proposal. The best safety rules will have no effect if they are not implemented and respected by the operators. To guarantee this, Europe needs strong oversight and enforcement of the rules it sets for the aviation sector.

While safety oversight will remain largely a Member State responsibility, it is important to introduce an additional layer of oversight – to be provided by the Agency. This will have a distinct added value in terms of safety, as Member States do not always show the eagerness vis-à-vis “their” operators on “their” airports that would be necessary for ensuring proper enforcement. The prospect of an EASA ramp inspection on their territory could stimulate this eagerness.

This issue is currently subject to intense discussions in the Council Working Group. It is too early to see if the new, completely rewritten Art. 7 will strengthen, rather than weaken the Commission’s proposal.

ECA strongly recommends to the EP to provide EASA with strong collective oversight and enforcement mechanism, to ensure safety rules are actually enforced and implemented. This should include the possibility for the Agency to carry out ramp inspections.

ECA will comment further and suggest amendments once the Council text has reached a stage where we can judge if it could serve the EP as a basis for its report.

Enforcement is more effective if there is a threat of **sanctions** for those who do not comply with the rules. These sanctions should be as uniform as possible throughout the EU.

ECA suggests that a reference is made in the 1592 Regulation to oblige Member States to introduce effective sanctions for non-compliance.

<u>Commission Proposal</u> Art. 7	<u>Proposed ECA Amendment</u> Art. 7, new para. 3
	3 (new). <u>Member States shall lay down penalties for infringement of this Regulation and its implementing rules. The penalties shall be effective, proportionate and dissuasive.</u>

7. Incident Reporting – Need for Protection of the Source of Information

The Commission proposes a new Article 11(a) related to incident investigations and occurrence reporting. It aims at ensuring that the source of any information received on a voluntary basis should not be revealed, that Member States shall refrain from starting proceedings against individuals and that employees should not be subject to any prejudice by their employer (unless in cases of gross negligence).

This provision on the “Protection of the Source of Information” is a central element of the 1592 proposal, and is strongly supported by ECA.

It is often the front end users (pilots and air traffic controllers) who report on safety incidents. It is their information that helps to identify safety gaps and to improve the safety system. If the reporters have to fear that they will be legally prosecuted or punished by their employers, they will not report, with the result that crucial safety information is not available for improving the system. The need for a *non-punitive* reporting system is widely recognised in the aviation sector.

However, the proposed text has two major shortcomings: First, it applies only to “voluntary” reporting, rather than to all forms of reporting, including mandatory reporting. The safety value of the incident information is the same. The same protection for the reporter is needed, irrespective of whether the report has been provided on a voluntary or on a mandatory basis.

ECA proposes that the protection of the source of information needs to apply also to *mandatory* reporting.

<u>Commission Proposal</u> Art. 11(a), para. 1	<u>Proposed ECA Amendment</u> Art. 11(a), para. 1
<p>1. When information referred to in Article 11 has been provided by a natural person on a voluntary basis, the reports shall not reveal the source of such information.</p>	<p>1. When information referred to in Article 11 has been provided by a natural person on a voluntary <u>or mandatory</u> basis, the reports shall not reveal the source of such information</p>

The second shortcoming is that the protection of the source of information applies only “*without prejudice to the applicable rules of penal law*” in Member States. In fact, while aviation stakeholders acknowledge the need for a *non-punitive* reporting system, it is the national judicial authorities whose “punitive” approach is in direct conflict with the safety interests in aviation. Based on their national penal law, many prosecutors can have access to incident reports and thereby reveal the source of information, and even legally prosecuting the reporter in case of assumed wrongdoings.

This problem is widely recognised and increasingly being addressed (e.g. by the Flight Safety Foundation, Eurocontrol, the Commission and Social Partners in the European Social Dialogue on air transport, etc.). In the short-term, there is little that can be done at EU level. However, a new Recital – in line with the current Council discussion – should address this issue in view of setting the direction of future legislative developments in Europe.

ECA suggests a new recital stressing the need for *non-punitive* in incident/occurrence reporting in Europe as well as the need for national penal law to be changed to that effect.

<u>Commission Proposal</u>	<u>Proposed ECA Amendment</u> New recital
	<p><u>(1) Promotion of a safety culture and the proper functioning of a regulatory system in the fields covered by this Regulation require that incidents and occurrences are spontaneously reported by their witnesses. Such reporting is only possible by the establishment of a non-punitive environment. Appropriate measures should be taken by Member States to provide for the protection of such information and of its reporters, inter alia by adapting their rules of penal law.</u></p>

8. Flexibility Provisions – Transparency & Safeguards Against Abuse

The Commission proposes to change the “Flexibility” provisions that allow Member States to deviate from the EASA rules under certain circumstances (Art. 10). The proposed changes are made to update the current provisions and to adapt them to the Agency’s grown competencies.

Flexibility provisions are an important tool to enable EASA, the Commission and EU Member States to quickly adapt their safety action e.g. to special situations and unforeseen circumstances.

However, the use of such flexibilities must take place in a transparent manner and only in clearly defined circumstances where the issue at stake can *not* be addressed within the framework of the 1592 regulation and its implementing rules. Crucially, any flexibilities granted must guarantee that safety is not compromised.

However, the proposed flexibility provisions lack transparency as well as sufficient safeguards against potential abuse by air operators keen to use “flexibilities” as a fast-track to change the rules.

To address these shortcomings, ECA suggests to tighten certain provisions, to have aviation stakeholders informed about flexibility decisions taken, and to set up a public registry for any such decisions taken and measures adopted.

8.1. Transparent Flexibility

The Commission proposals foresees flexibility measures in three circumstances:

- 1) unforeseen (or immediate) safety problems,
- 2) unforeseen operational circumstances or needs of a limited duration,

- 3) derogations to achieve an equivalent safety level by other means (see further down).

Given the large number of air operators in the EU, and the many situations where they may want to, or have asked for flexibilities, the number of decisions related to flexibilities and measures adopted could be important.

For aviation industry stakeholders, interested bodies, such as the European Parliament, and for the travelling public at large, it is important to keep track of the decisions and measures adopted, as well as the reasons for adopting them. However, the current procedures are little transparent, take place within closed expert circles and do not allow for stakeholder consultation.

ECA proposes a new paragraph requiring aviation stakeholders to be informed of any flexibility decisions and EASA to set up a public registry (e.g. on its website), including the measures adopted/revoked and the reasons therefore.

<u>Commission Proposal</u> Art. 10	<u>Proposed ECA Amendment</u> Art. 10
	New paragraph (7) <u>(7) The Agency shall inform aviation stakeholders and set up a publicly accessible registry of any decisions taken under Article 10, the reasons therefore, and any measures adopted or revoked pursuant to such decisions.</u>

8.2. Derogations to Achieve Equivalent Safety Levels by Other Means

The Commission proposes (Art.10 (5)) that Member States may grant approval to an operator's for measures derogating from EASA implementing rules (IR), as long as these measures guarantee the same level of safety protection as the IR. To be able to grant such approval, EASA must give an opinion, while the Commission take the final decision.

However, the level of "proof" to be provided by the Member State when notifying the Agency and Commission is too low, as is the need to provide convincing "mitigating factors", i.e. measures that compensate for the potential safety risk created by the derogation.

ECA proposes to strengthen the provisions on permanent derogations from EASA rules to reduce the risk of them being abused for specific interests.

<p align="center"><u>Commission Proposal</u></p> <p align="center">Art. 10 (5)</p>	<p align="center"><u>Proposed ECA Amendment</u></p> <p align="center">Art. 10 (5)</p>
<p>Where an equivalent level of protection to that attained by the application of the rules implementing this Regulation can be achieved by other means, a Member State may, without discrimination on grounds of nationality, grant approval derogating from those implementing rules.</p> <p>In such cases, the Member State shall notify the Agency and the Commission that it intends to grant such approval and shall give reasons demonstrating the need to derogate from the rule concerned, as well as the conditions laid down to ensure that an equivalent level of protection is achieved.</p>	<p>Where an equivalent level of <u>safety</u> protection to that attained by the application of the rules implementing this Regulation can be achieved by other means, a Member State may, without discrimination on grounds of nationality, grant approval derogating from those implementing rules.</p> <p>In such cases, the Member State shall notify the Agency and the Commission that it intends to grant such approval and shall give reasons demonstrating the need to derogate from the rule concerned, <u>the impossibility to address this need within the framework of this Regulation and its implementing rules</u>, as well as the conditions laid down to ensure that an equivalent level of protection is achieved, <u>including suitable mitigating factors where appropriate</u>.</p>

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