

Commission Delegated Regulation (EU) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems

COMMISSION DELEGATED REGULATION (EU) 2019/945

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THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91⁽¹⁾, and in particular Article 58 and Article 61 thereof,

Whereas:

- (1) The unmanned aircraft systems ('UAS') whose operation presents the lowest risks and that belong to the 'open' category of operations should not be subject to classic aeronautical compliance procedures. The possibility to establish Community harmonisation legislation as referred to in paragraph 6 of Article 56 of Regulation (EU) 2018/1139 should be used for those UAS. Consequently, it is necessary to set out the requirements that address the risks posed by the operation of those UAS, taking full account of other applicable Union harmonisation legislation.
- (2) These requirements should cover the essential requirements provided for in Article 55 of Regulation (EU) 2018/1139, in particular as regards the specific features and functionalities necessary to mitigate risks pertaining to the safety of the flight, privacy, and protection of personal data, security or the environment, arising from the operation of these UAS.
- (3) When manufacturers place a UAS on the market with the intention to make it available for operations under the 'open' category and therefore affix a class identification label on it, they should ensure compliance of the UAS with the requirements of that class.
- (4) Considering the good level of safety achieved by model aircraft already made available on the market, it is appropriate to create the C4 class of UAS which should not be subject to disproportionate technical requirements for the benefit of model aircraft operators.
- (5) This Regulation should also apply to UAS, which are considered as toys within the meaning of Directive 2009/48/EC of the European Parliament and of the Council⁽²⁾. Those UAS should also comply with Directive 2009/48/EC. That compliance

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requirement should be taken into account when defining additional safety requirements under this Regulation.

- (6) UAS that are not toys within the meaning of Directive 2009/48/EC should comply with the relevant essential health and safety requirements set out in Directive 2006/42/EC of the European Parliament and of the Council⁽³⁾ in so far as this Directive applies to them, to the extent that those health and safety requirements are not intrinsically linked to the safety of the flight by UAS. Where those health and safety requirements are intrinsically linked to the safety of the flight, only this Regulation should apply.
- (7) Directive 2014/30/EU⁽⁴⁾ and Directive 2014/53/EU⁽⁵⁾ of the European Parliament and of the Council should not apply to unmanned aircraft that are subject to certification according to Regulation (EU) 2018/1139, are exclusively intended for airborne use and intended to be operated only on frequencies allocated by the Radio Regulations of the International Telecommunication Union for protected aeronautical use.
- (8) Directive 2014/53/EU should apply to unmanned aircraft that are not subject to certification and are not intended to be operated only on frequencies allocated by the Radio Regulations of the International Telecommunication Union for protected aeronautical use, if they intentionally emit and/or receive electromagnetic waves for the purpose of radio communication and/or radiodetermination at frequencies below 3 000 GHz.
- (9) Directive 2014/30/EU should apply to unmanned aircraft that are not subject to certification and are not intended to be operated only on frequencies allocated by the Radio Regulations of the International Telecommunication Union for protected aeronautical use, if they do not fall within the scope of Directive 2014/53/EU.
- (10) Decision No 768/2008/EC of the European Parliament and of the Council⁽⁶⁾ sets out common principles and horizontal provisions intended to apply to marketing of products that are subject to relevant sectorial legislation. In order to ensure consistency with other sectorial product legislation, the provisions on the marketing of UAS intended to be operated in the ‘open’ category should be aligned with the framework established by Decision 768/2008/EC.
- (11) Directive 2001/95/EC of the European Parliament and of the Council⁽⁷⁾ applies to safety risks of UAS so far as there are no specific provisions with the same objective in rules of Union law governing the safety of the products concerned.
- (12) This Regulation should apply to all forms of supply, including distance selling.
- (13) Member States should take the necessary steps to ensure that UAS intended to be operated in the ‘open’ category are made available on the market and put into service only where they do not compromise the health and safety of persons, domestic animals or property, when normally used.
- (14) In order to provide citizens with high level of environmental protection, it is necessary to limit the noise emissions to the greatest possible extent. Sound power limitations applicable to UAS intended to be operated in the ‘open’ category might be reviewed at

the end of the transitional periods as defined in Commission Implementing Regulation (EU) 2019/947⁽⁸⁾.

- (15) Special attention should be paid to ensure compliance of products in the context of an increase of e-commerce. To that end, Member States should be encouraged to pursue cooperation with the competent authorities in third countries and to develop cooperation between market surveillance authorities and customs authorities. Market surveillance authorities should make use, when possible, of the ‘notice and action’ procedures and establish cooperation with their national authorities competent for the implementation of Directive 2000/31/EC of the European Parliament and of the Council⁽⁹⁾. They should establish close contacts allowing rapid response with key intermediaries that provide hosting services for products sold online.
- (16) In order to ensure a high level of protection of public interest, such as health safety, and to guarantee fair competition on the Union market, economic operators should be responsible for the compliance of UAS intended to be operated in the ‘open’ category with the requirements laid down in this Regulation, in relation to their respective roles in the supply and distribution chain. Therefore, it is necessary to provide a clear and proportionate distribution of obligations, which corresponds to the role of each economic operator in the supply and distribution chain.
- (17) In order to facilitate communication between economic operators, national market surveillance authorities and consumers, economic operators supplying or distributing UAS intended to be operated in the ‘open’ category should provide a website address in addition to the postal address.
- (18) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure of UAS intended to be operated in the ‘open’ category. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (19) This Regulation should apply to any UAS intended to be operated in the ‘open’ category that is new to the Union market, whether a new UAS made by a manufacturer established in the Union or a new or second-hand UAS imported from a third country.
- (20) It is necessary to ensure that UAS from third countries entering the Union market comply with the requirements of this Regulation if they are intended to be operated in the ‘open’ category. In particular, it should be ensured that manufacturers carry out appropriate conformity assessment procedures. Provision should therefore be made for importers to make sure that the UAS they place on the market comply with the requirements of this Regulation and that they do not place on the market UAS which do not comply with these requirements or present a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by the manufacturers is available for inspection by the competent national authorities.
- (21) The distributor who makes a UAS intended to be operated in the ‘open’ category available on the market should act with due care to ensure that its handling of the product does not adversely affect its compliance. Both importers and distributors are expected

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- to act with due care in relation to the requirements applicable when placing or making products available on the market.
- (22) When placing on the market a UAS intended to be operated in the ‘open’ category, every importer should indicate on the UAS his name, registered trade name or registered trademark and the address at which he can be contacted. Exceptions should be provided for cases where the size of the UAS does not allow this. This includes cases where the importer would have to open the packaging to put his name and address on the UAS.
- (23) Any economic operator that either places a UAS intended to be operated in the ‘open’ category on the market under his own name or trademark, or modifies a UAS intended to be operated in the ‘open’ category in such a way that compliance with the applicable requirements may be affected, should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (24) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all the necessary information relating to the UAS intended to be operated in the ‘open’ category.
- (25) Ensuring the traceability of a UAS intended to be operated in the ‘open’ category throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities’ task of tracing economic operators who make non-compliant UAS available on the market.
- (26) This Regulation should be limited to the setting out of the essential requirements. In order to facilitate the assessment of conformity of UAS intended to be operated in the ‘open’ category with those requirements, it is necessary to provide for a presumption of conformity for products, which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council⁽¹⁰⁾ for the purpose of setting out detailed technical specifications of those requirements.
- (27) The essential requirements applicable to UAS intended to be operated in the ‘open’ category should be worded precisely enough to create legally binding obligations. They should be formulated so as to make it possible to assess conformity with them even in the absence of harmonised standards or where the manufacturer chooses not to apply a harmonised standard.
- (28) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of the harmonisation legislation applicable to UAS intended to be operated in the ‘open’ category under this Regulation. This procedure should apply where appropriate in relation to standards which reference have been published in the Official Journal as providing presumption of conformity with the requirements laid down in this Regulation.
- (29) To enable economic operators to demonstrate and the competent authorities to ensure that UAS intended to be operated in the ‘open’ category made available on the market

comply with the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC sets out modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectorial coherence and to avoid ad hoc variants of conformity assessment, conformity assessment procedures should be chosen from among those modules.

- (30) Market surveillance authorities and UAS operators should have easy access to the EU declaration of conformity. In order to fulfil this requirement, manufacturers should ensure that each UAS intended to be operated in the ‘open’ category is accompanied either by a copy of the EU declaration of conformity or by the internet address at which the EU declaration of conformity can be accessed.
- (31) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts for UAS intended to be operated in the ‘open’ category should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.
- (32) The CE marking indicating the conformity of a product is the visible consequence of a whole process of conformity assessment in the broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008 of the European Parliament and of the Council⁽¹¹⁾. Rules governing the affixing of the CE marking to UAS intended to be operated in the ‘open’ category should be laid in this Regulation.
- (33) Some UAS classes intended to be operated in the ‘open’ category covered by this Regulation require the intervention of conformity assessment bodies. Member States should notify the Commission of these.
- (34) It is necessary to ensure a uniformly high level of performance of bodies performing conformity assessments of UAS intended to be operated in the ‘open’ category throughout the Union, and that all such bodies perform their functions at the same level and under conditions of fair competition. Therefore, obligatory requirements should be set for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (35) If a conformity assessment body demonstrates conformity of UAS intended to be operated in the ‘open’ category with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.
- (36) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (37) Regulation (EC) No 765/2008 sets out rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and sets out the general principles of the

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- CE marking. The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008.
- (38) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be used by national public authorities throughout the Union as the means of demonstrating the technical competence of conformity assessment bodies.
- (39) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the UAS intended to be operated in the ‘open’ category to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies do in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and performance of bodies to be notified, and the monitoring of bodies already notified, also cover activities carried out by subcontractors and subsidiaries.
- (40) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (41) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified, before they start operating as notified bodies.
- (42) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary administrative burden for economic operators. For the same reason, and also to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. This can best be achieved through appropriate coordination and cooperation between notified bodies.
- (43) Interested parties should have the right to appeal against the result of a conformity assessment carried out by a notified body. It is important to ensure that an appeal procedure against all decisions taken by notified bodies is available.
- (44) Manufacturers should take all appropriate measures to ensure that UAS intended to be operated in the ‘open’ category may be placed on the market only if, when properly stored and used for their intended purpose or under conditions, which can be reasonably foreseen, it does not endanger people's health or safety. UAS intended to be operated in the ‘open’ category should be considered as non-compliant with the essential requirements set out in this Regulation only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.
- (45) In order to ensure legal certainty, it is necessary to clarify that the rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008, including the provisions regarding the exchange

of information through the Rapid Alert System (RAPEX), apply to UAS intended to be operated in the ‘open’ category. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks. In order to ensure a smooth transition as regards the implementation of this Regulation, appropriate transitional measures should be provided.

- (46) UAS whose operation present the highest risks should be subject to certification. This Regulation should therefore define the conditions under which the design, production and maintenance of UAS should be subject to certification. Those conditions are linked to a higher risk of harm to third persons in case of accidents and therefore certification should be required for UAS designed to transport people, UAS designed to transport dangerous goods and for UAS that has any dimension above 3 m and is designed to be operated over assemblies of people. Certification of UAS used in the ‘specific’ category of operations defined in Implementing Regulation (EU) 2019/947 should also be required if, following a risk assessment, an operational authorisation issued by the competent authority considers that the risk of the operation cannot be adequately mitigated without the certification of the UAS.
- (47) UAS placed on the market and intended to be operated in the ‘open’ category and bearing a class identification label should comply with the certification requirements for UAS operated in the ‘specific’ or ‘certified’ categories of operations, as applicable, if those UAS are used outside the ‘open’ category of operations.
- (48) UAS operators that have their principal place of business, are established, or are resident in a third country and that conduct UAS operations within the single European sky airspace should be subject to this Regulation.
- (49) The measures provided for in this Regulation are based on Opinion No 01/2018⁽¹²⁾ issued by the European Union Aviation Safety Agency (EASA) in accordance with Article 65 of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

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- (1) [OJ L 212, 22.8.2018, p. 1.](#)
- (2) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys ([OJ L 170, 30.6.2009, p. 1.](#))
- (3) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC ([OJ L 157, 9.6.2006, p. 24.](#))
- (4) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility ([OJ L 96, 29.3.2014, p. 79.](#))
- (5) Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC ([OJ L 153, 22.5.2014, p. 62.](#))
- (6) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC ([OJ L 218, 13.8.2008, p. 82.](#))
- (7) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety ([OJ L 11, 15.1.2002, p. 4.](#))
- (8) Commission Implementing Regulation (EU) 2019/947 of 24 May 2019 on the rules and procedures for the operation of unmanned aircraft (see page 45 of this Official Journal).
- (9) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') ([OJ L 178, 17.7.2000, p. 1.](#))
- (10) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ([OJ L 316, 14.11.2012, p. 12.](#))
- (11) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ([OJ L 218, 13.8.2008, p. 30.](#))
- (12) EASA Opinion No 01/2018 'Introduction of a regulatory framework for the operation of unmanned aircraft systems in the "open" and "specific" categories' (RMT.0230), available at <https://www.easa.europa.eu/document-library/opinions>

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