applied sciences

MDPI

Article

Release of Sterile Mosquitoes with Drones in Urban and Rural Environments under the European Drone Regulation

Manuel Garcia [1], Ivan Maza [1,*], Anibal Ollero [1], Daniel Gutierrez [2], Idoia Aguirre [3] and Antidio Viguria [4]

[1] GRVC Robotics Laboratory, University of Seville, Avda. de los Descubrimientos, s/n, 41092 Seville, Spain; manuel.garcia.rivero@gmail.com (M.G.); aollero@us.es (A.O.)
[2] Instituto Tecnológico de Galicia, c/Cantón Grande 9, Planta 3, 15003 La Coruña, Spain; dgutierrez@itg.es
[3] Centro Tecnológico de Automoción y Mecatrónica, c/Cantón Grande 9, Planta 3, Plaza Cein 4, 31110 Noain, Spain; info@naitec.es
[4] Advanced Center for Aerospace Technologies, c/Wilbur y Orville Wright 19, La Rinconada, 41300 Seville, Spain; aviguria@catec.aero
* Correspondence: imaza@us.es

Featured Application: Drones can be a very useful tool to help mosquito control tasks in areas where these insects are an important vector of disease transmission. Storing sterile mosquitoes in drones and releasing them in targeted areas where previous suppression of wild populations has been performed can be a major advance in this methodology. This is part of the sterile insect techniques (SIT) which have been demonstrated to be an environmentally friendly solution for the control of insect pests. However, the use of drones in the areas where these operations are foreseen is limited by the fact that we have a regulation that advances at a slower pace than technology. Of particular interest is the case of the suppression of mosquito populations in urban areas below the transmission threshold, where drones and their operating conditions must meet demanding safety requirements. This article presents the current regulatory situation in Europe that affects drone operations and its applicability to the case of the release of sterile mosquitoes to control the population of these insects in two different scenarios: urban and rural areas.

Abstract: In recent years, several countries have developed the use of sterile insect techniques (SIT) to fight against mosquitoes that transmit diseases. From a technical and economic point of view, the use of drones in the aerial release of sterile mosquitoes leads to important improvements in aerial coverage and savings in operational costs due to the requirement of fewer release sites and field staff. However, these operations are under the European drone regulation, one of the most advanced in the world. The main contribution and novelty of this paper with respect to previous work is the analysis of the SIT application with drones under the European risk-based regulation in two scenarios: urban and rural areas. The specific operations risk assessment (SORA) methodology has been applied to assess the risk of drone operations in these scenarios. The paper presents the operational requirements for aerial release of mosquitoes with drones along with the regulatory considerations that must be applied. Finally, an overview of the conditions in operation that could relax risks and mitigation measures is also discussed.

Keywords: mosquitoes' control; drones; drone regulation; unmanned aircraft systems (UAS); U-space; SORA methodology; sterile insect technique (SIT)

Citation: Garcia, M.; Maza, I.; Ollero, A.; Gutierrez, D.; Aguirre, I.; Viguria, A. Release of Sterile Mosquitoes with Drones in Urban and Rural Environments under the European Drone Regulation. *Appl. Sci.* **2022**, *12*, 1250. https://doi.org/10.3390/app12031250

Academic Editor: Augusto Ferrante

Received: 6 December 2021
Accepted: 14 January 2022
Published: 25 January 2022

1. Introduction

Mosquitoes are considered one of the deadliest reservoirs of vector borne disease in the world. According to the World Health Organisation (WHO), several million of deaths and hundreds of millions of cases occur each year from mosquito-borne diseases. Mosquito control is essential to reduce the transmission of diseases such as malaria, dengue fever, and Zika. In [1] the main, mosquito-borne diseases are shown with a summary of statistics and places where mosquito pest control is essential.

Different techniques have been used in recent years to control mosquitoes that transmit human disease. Most mosquito control techniques require the use of insecticides with high costs associated in terms of personnel and time. Furthermore, the presence of these toxic products has a large impact not only on human health but also on the environment. Concerns about resistance to pyrethroids in recent years [2] have led researchers to explore alternative solutions, such as the sterile insect technique (SIT) for mosquito control. The release of sterile insects to contain and suppress [3] mosquito populations was proposed by Dahmana and Mediannikov (2020) [4]. This technology has been used for a long time, for example, in 1980 in a program in El Salvador [5], but the required logistics have limited its applicability in practice.

The use of drones is seen as a promising tool for the release of sterile insect populations into targeted environments. Furthermore, these releases are carried out repeatedly over a certain period. The ease of use of drones and their ability to access any environment from the air make them a viable system in this mosquito control technique. Drones may provide a means of releasing sterile mosquitoes over large areas due to the ability of drones to travel long distances in short periods of time. A standard DJI Phantom 4 type light drone can fly for 25 min, being able to travel up to 25 km. Furthermore, one of the main advantages of using drones is that they can reach inaccessible areas where humans cannot.

There are some interesting works on this aspect. In [6] a fully automated system for releasing adult mosquitoes with a DJI M600 drone in a region of Brazil was reported. The system enabled a homogeneous dispersal of sterile male *Aedes aegypti* while maintaining their quality, leading to a homogeneous sterile-to-wild male ratio due to their aggregation at the same sites. This article concluded that the use of drones for the release of sterile mosquitoes leads to important improvements in aerial coverage and savings in operational costs due to the requirement of fewer release sites and field staff. One of the first works in this direction, dating back to 2017, can be found in [7] when the WeRobotics organization modified a DJI Matrice 600 drone to integrate a sterile mosquito release mechanism.

The effect of storage conditions on the survival of male Aedes aegypti mosquitoes during transport was studied in [8]. During transport from the rearing facility to the release site and during actual release in the field, damage to male mosquitoes should be minimized to preserve their reproductive competitiveness. The short flight range of male Aedes aegypti requires elaborate release strategies, such as release via drones. The authors conducted shipping in a 'real-life' setting to determine a good storage temperature and a compaction rate for the survival of the mosquitoes. In [9], optimized chilling conditions for handling male adults of *Aedes albopictus* prior to release were analyzed. The authors claimed that further studies are required to develop drone release systems specific for chilled mosquitoes to improve release efficiency, as well as to compare the population suppression efficiency between release of postchilled and nonchilled males in the field. In any case, the weight of the payload for the UAS was not high and some low-cost solutions [10,11] could be applied.

The sterile insect technique is also used to control the codling moth pests and the authors of [12] evaluated the use of small uncrewed aircraft systems (UAS) for the release of sterile codling moths. Sterile codling moths released from higher altitudes were more widely distributed and drifted more in strong winds, compared to those released from lower altitudes. Most of the released insects were recaptured in a 50 m wide swath under the release route. Recapture rates for aerially released insects were 40–70% higher compared to those released from the ground. The authors claimed that drones provide a promising alternative to ground release and conventional aircraft for the release of sterile codling moths. For the same pest, in [13] the authors compared the recapture rate of sterile moths following their release by four methods, and the efficiency of each system. The methods were the following: a fixed-wing unmanned plane flying ~40–45 m high at 70 km/h, an unmanned hexacopter travelling 20 m high at 25 km/h, and manually from the ground via bicycles or motor vehicles. The highest recapture rate followed delivery by hexacopter, then bicycle, vehicle, and plane, whereas the methods in ascending order of time per hectare for delivery were the following: plane and vehicle, hexacopter, then bicycle.

From an analysis of the state of the art, drone technology is mature enough from a technical point of view to perform the SIT application. However, the use of drones for the release of sterile insects is affected by the new regulation that has been approved at the European level [14] and came into force in January 2021. Then, the main contribution and novelty of this paper with respect to previous work is the risk analysis needed to put this application in practice with drones in rural and urban areas under the European drone regulation.

The European Aviation Safety Agency (EASA) is responsible for implementing, maintaining and monitoring compliance with newly established rules. Historically, each European Union (EU) member state maintained its own drone regulation at national level. Recently, a new EU regulation was approved that affects all member states equally. This new regulation was developed in the spirit of harmonizing rules and promoting the growth of the drone sector. The European regulation applies to any drone regardless of its mass and use. Drone operations are classified according to risk and are broken down into three operational categories. Table 1 shows this categorization.

Table 1. Categorization of drone operations in the new European regulation.

Category	Risk
Open	Low-risk operation
Specific	Medium-risk operation
Certified	High-risk operation, similar to manned aviation operations

In addition to this, EASA has published the acceptable means of compliance (AMC) and guidance material (GM) [15], which complement the regulation and explains in detail the different categories set out above. The document entitled Specific Operations Risk Assessment (SORA) details the methodology for assessing the risk of drone operations. In this regard, several papers about risk analysis and SORA can be found in the literature. Reference [16] analyzes the application of SORA for a multi-UAS airframe inspection (AFI) operation, which involves the deployment of multiple UAS with autonomous features within an airport. In [17], the authors present the most important risks related to conducting operations with the use of UAS by first responders (FRs), while reference [18] presents the application of the SORA methodology for media production with a small UAS team. In addition, [19] describes the application of SORA to the flight of large remotely piloted aircraft systems (RPAS) in Australian airspace highlighting its distinguishing factors.

The paper is structured as follows. First, the current European drone regulation will be explained in detail in Section 2. Materials and methods are described in Section 3, where the SORA methodology will be shown as a basis to assess the risk of drone operation and help categorize the operation. Then, the concept of U-Space will be introduced in Section 4 since it is the framework that will help integrate drone operations into the airspace. Section 5 explains the results of the application of the SORA methodology to some typical mosquito-related operations. Finally, Section 6 closes the paper with a discussion of the analysis.

2. Current European Drone Regulation

As mentioned above, the European Commission adopted a new set of provisions for the use of drones within the Single European Sky strategy, which is an initiative of the European Commission aiming to reform the current air traffic management system in most of Europe. The aim is not only to guarantee standards on the safety, efficiency, and environmental impact of the air traffic, but also to integrate drones safely into airspace.

EU legislation has been radically amended in recent years. In July 2018, European lawmakers passed the new Regulation (EU) 2018/1139 on common rules in the field of civil aviation, which included a new mandate for the EU EASA on drones and urban air mobility [14]. This regulation adopts a new comprehensive legal strategy for the drone sector and repeals Reg. (EC) 2008/216 [20], which only concerned drones with a take-off weight of more than 150 kg, while drones with a maximum take-off weight of less than 150 kg were within the jurisdiction of the member states.

Since neither the EU Parliament nor the EU Council had any objections, both the Implementing and Delegated Acts (Commission Delegated Regulation (EU) 2019/945 [21] and Commission Implementing Regulation (EU) 2019/947 [22]) were published in June 2019 and entered into force on 1 July 2019. Drone operators were required to register either in the member state of their residence or where the drone operator registered their main place of business by July 2020. These regulations were gradually enforced over the course of a one-year transition period from their date of publication. This transition period provided Member States and drone operators with time to prepare before full regulatory enforcement in 2022.

The new EU regulatory framework covers all types of existing and future drone operations, enabling operators—once authorized in their state of registration—to freely circulate between Member States. The purpose of introducing these new regulations is to ensure the safety of drone operations, as well as to protect the privacy of EU citizens, with respect to personal data protection and the environment while allowing free access to airspace. The new regulations establish technical and operational requirements, provisions for drone operations, and personnel (minimum requirements and operator training), including both pilots and organizations. The EU regulatory framework defines drone capabilities, types of operation and labels these into three broad risk-based categories (open, specific, and certified) following the distinction suggested by EASA in the Opinion 01/2018 [23]. These three categories of operations are based on the levels of risk involved per drone flight, and each adopts a varied regulatory approach, with drone flight operational limitations decreasing with the requirement for greater authorization from a member state's national aviation authority.

Regulation 2019/947 presents a comprehensive system of unified legal regulations that classifies drone operations into the above-mentioned three categories based on different criteria:

- Open (Article 4 of Regulation 2019/947). Operations in this category shall not be subject to any prior operational authorization, nor to an operational declaration by the drone operator before the operation if the following conditions are met. The drone belongs to one of the classes set out in the Delegated Regulation (EU) 2019/945 or is privately built or meets the conditions defined in Article 20 of Regulation 2019/947. The unmanned aircraft has a maximum take-off mass of less than 25 kg, and the remote pilot keeps the unmanned aircraft in visual line of sight (VLOS) conditions at all times except when flying in follow-me mode or when using an unmanned aircraft observer. During open operations, the remote pilot ensures that the unmanned aircraft is maintained within 120 m from the closest point on the surface of the Earth (except when it overflies an obstacle upon request to its owner) and at a safe distance from people (never flying over crowds). The unmanned aircraft cannot carry dangerous goods and does not drop any material. Open operations are further divided into three subcategories: A1 (fly over people), A2 (fly close to people) and A3 (fly far from people).
- Specific (Article 5 of Regulation 2019/947). Operations fall into this category as long as the concept of operation exceeds the limitations defined in the open category. The drone operator shall apply to obtain an operational authorization from the competent authority in the member state where it is registered, submitting a risk assessment including adequate mitigating measures. This risk assessment approach allows handling new technologies and operations such as beyond visual line of sight (BVLOS), fully autonomous drones, urban areas, etc. However, if the operation complies with one of the standard scenarios (STS) defined by EASA, the drone operator shall not be

required to obtain the above-mentioned operational authorization, and a declaration (responsible) by the drone operator will be sufficient. EASA has defined two STS:

  - STS01: VLOS operation in a controlled ground area in an urban environment;
  - STS02: BVLOS operation in a controlled ground area in a sparsely populated environment.

  Apart from that, an operational authorization or a declaration shall not be required for drone operators holding a light UAS operator certificate (LUC) with appropriate privileges, which is valid in all EU member states without additional demonstrations.

- Certified (Article 6 of Regulation 2019/947). An operation is classified as being in the certified category when, according to the risk assessment, the operation cannot take place without a certificate for the operator, a certificate for the airworthiness of the drone, and a license for the remote pilot (unless fully autonomous). In any case, the following operations are within the certified category: operations over assemblies of people with an aircraft of characteristic dimensions of 3 m or more, transportation of people, and transportation of dangerous goods if, in case of accident, they pose a high risk for third parties.

In October 2019, EASA published its guidance material (GM) and a description of the means of complying with the regulation (acceptable means of compliance (AMC)). The AMC shed light on how to carry out the SORA, which is required for operation, depending on the 'specific' category under scrutiny. Along the same lines, EASA has published some predefined risk assessments as AMC to Article 11, to cover most common drone operations. The intent is to simplify the burden for drone operators, paving the way for the full implementation of the new legal framework.

Finally, there are some points to be remarked: there is no distinction between professional and leisure activities with drones or between experimental flights and aerial works.

3. Materials and Methods: The SORA Risk Analysis Methodology

In the current regulatory framework for drones or UAS in Europe, a risk-based approach is used to assess the safety of drone operations. The SORA methodology has been developed by the Joint Authorities for Rulemaking of Unmanned Systems (JARUS) and focuses primarily on the specific category.

The SORA is a multistage process of risk assessment aiming at risk analysis of certain unmanned aircraft operations, as well as defining necessary mitigations and levels of robustness. The application of this methodology is an acceptable means of evaluating the risks associated with the operation of a drone within the specific category and to determine the acceptability of the proposed operation. In this section, a general description of the SORA methodology is presented.

3.1. Introduction to SORA

JARUS pursues a consensus from various national aviation authorities and stakeholders on a common procedure to identify and qualitatively assess safety risks for drone operations. In particular, JARUS developed SORA [24] in 2019.

Any risk assessment methodology uses a schema based on the ISO 31000 standard, providing a reference framework and guiding the general risk management process (see Figure 1).

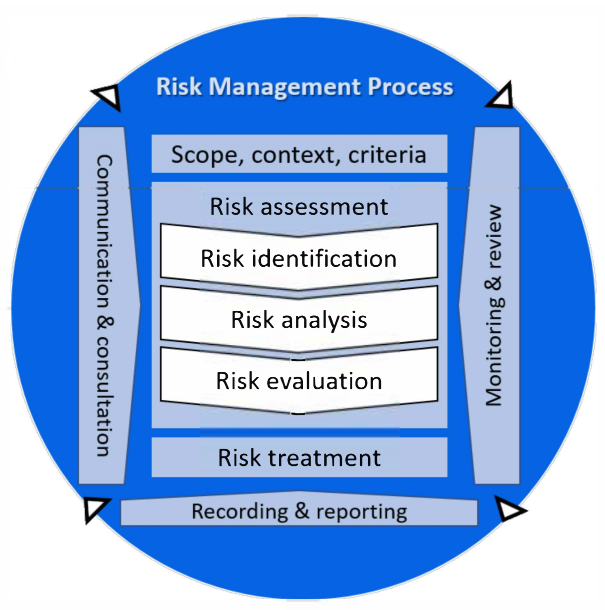

Figure 1. General aspects of risk management from ISO 31000. The risk management process involves the systematic application of policies, procedures and practices to the activities of communicating and consulting, establishing the context and assessing, treating, monitoring, reviewing, recording and reporting risk.

SORA is a method based on a holistic risk model that provides a generic framework to identify possible hazards and threats, as well as relevant harm and threat barriers applicable to drone operation. The aim is to establish a sufficient level of confidence that a specific operation can be carried out safely. To achieve this, SORA requires first the applicant to collect and provide the relevant technical, operational, and system information needed to assess the risk associated with the intended operation of the drone.

Some key aspects related to the applicability of the methodology are the following.

- It aims to assess the safety risks involved in the operation of drones of any class, size, and type of operation and particularly suited, but not limited to 'specific' operations for which a risk and hazard assessment is required.
- The safety risks associated with collisions between drones and manned aircraft are within the scope of the methodology.
- Security aspects are excluded when not limited to those confined by the airworthiness of the systems (e.g., aspects relevant to the protection from unlawful electromagnetic interference).
- Privacy aspects are excluded from the applicability of this methodology.

3.2. The SORA Process

The SORA methodology provides a logical process for analyzing the proposed concept of operations (ConOps) and establishing an adequate level of confidence that the operation can be conducted with an acceptable level of risk. There are ten steps that support the SORA methodology, as shown in Figure 2. The process begins with the ConOps description, which provides the relevant technical, operational, and system information needed to assess the risk associated with the intended operation of the drone, both ground risk and air risk.

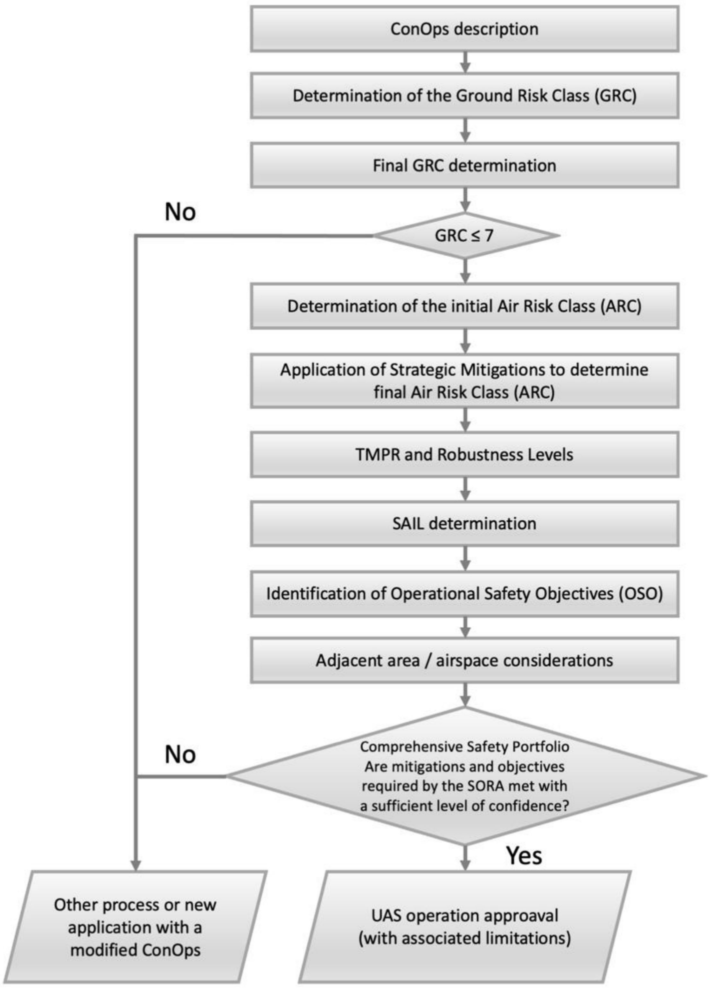

Figure 2. The SORA process adapted from [24] shows the ten steps that support the SORA methodology.

The ground risk class (GRC) is the intrinsic ground risk of the drone related to the risk of a person being struck by the drone (in the case of loss of drone control with a reasonable assumption of safety). To compute it, the applicant needs to identify the maximum drone characteristic dimension (e.g., wingspan for fixed wing, blade diameter for rotorcraft, maximum dimension for multicopters, etc.) and the knowledge of the intended operational scenario (VLOS or BVLOS; population density of the overflown areas). Intrinsic risks can be controlled and reduced by mitigations. The mitigations used to modify the intrinsic GRC have a direct effect on the safety objectives associated with a particular operation and, therefore, are important to ensure its robustness. The final determination of the GRC is based on the availability of these mitigations for operation.

The air risk class (ARC), understood as the intrinsic risk of mid-air collision, determines the air risk category. Identification of the ARC must take into account the impact on other air traffic and air traffic management (the altitude of the operation; controlled versus uncontrolled airspace; aerodrome versus non-aerodrome environment; airspace over urban versus rural environment). The ARC may be lowered by applying strategic and tactical mitigation means (detect and avoid systems or alternate means) resulting in the residual ARC. Strategic conflict strategies will deal with the planning at a global level of the route that the drone must follow to execute the mission, while tactical conflict strategies will deal with reactive local maneuvers that are executed during the flight to fulfill certain functionalities, such as avoiding possible encounters with other aircraft.

After determining the final GRC and residual ARC, it is now possible to derive the specific assurance and integrity levels (SAIL) associated with the proposed ConOps. The

SAIL represents the level of confidence that the operation will remain under control. On the other hand, the SAIL is also used to evaluate the defenses within the operation in the form of operational safety objectives (OSO) and to determine the associated level of robustness. These OSOs appear in the SORA as a list of objectives that have historically been used to ensure safe drone operations regarding technical issues, external systems supporting the operation, the effects of human errors, and the effects of adverse operating conditions.

In this paper we address two different scenarios that are highly representative of mosquitoes-related operations. First, it is considered the case of an urban environment targeted for a SIT mosquito program. Usually, large cities and their surroundings are immersed within the airspace associated with airports. Therefore, the operation is considered to be carried out in controlled airspace. The following conditions for the urban scenario constitute the ConOps for this case:

- VLOS: The operation takes place within the visual line of sight of the pilot;
- Moderately populated environment;
- Inside of controlled airspace;
- VLL: very low level operation, flights below 150 m of altitude.

The other case is in rural environments, without people around, which are aligned with population control in areas where this type of insect reproduces: lakes, humid areas, areas with dense vegetation, etc. In this case, the operational conditions that are considered as inputs for the ConOps are the following:

- BVLOS: the operation takes place beyond the visual line of sight of the pilot, without observers who can help the pilot;
- Sparsely populated environment;
- Out of controlled airspace;
- VLL: very low level operation, flights below 150 m of altitude.

4. Integration into Airspace (U-Space)

As indicated in [25], the expected number of drone operations in the European market is expected to reach 10 billion euros per year by 2035 and more than 15 billion euros per year by 2050. This volume of operations will pose safety, security and airspace integration issues in European airspace, especially at low flight levels (which are currently defined as altitudes below 150 m) with drones belonging mostly to open and specific categories.

Many organizations are iteratively maturing their approach to address this volume of drone operations, as outlined in various concepts developed by bodies such as the Single European Sky Airspace Research (SESAR) Joint Undertaking (JU) through the CORUS project [26], the Federal Aviation Administration (FAA) [27], and global standardization bodies such as the Global UTM Association (GUTMA) [28].

In Europe, safe drone traffic management and its safe operation within the existing air traffic environment in a harmonized manner across the European airspace are ensured by U-space (outside Europe, this concept is commonly referred to as unmanned traffic management or UTM). In [29], SESAR JU defined U-space in a blueprint as a set of services based on high levels of digitization, as well as automation of functions and procedures designed to guarantee access to airspace for a large number of drones in a safe and efficient way, with an initial focus on operations at very low levels (VLL), with a maximum height above ground level of 150 m. Then, U-space is a technological framework designed to facilitate any type of operation, in all classes of airspace and in any environment, even the most congested, while providing an appropriate interface for manned aviation and air traffic control.

The ConOps (concept of operations) for U-space was developed in the CORUS project and published on 30 September 2019 [26]. CORUS was focused on drones belonging to open or specific categories that operate in VLL, which are split into three types according to the services provided (see Figure 3):

- X: No conflict resolution service is offered;

- Y: Only preflight conflict resolution is offered;
- Z: Preflight conflict resolution and in-flight separation are offered.

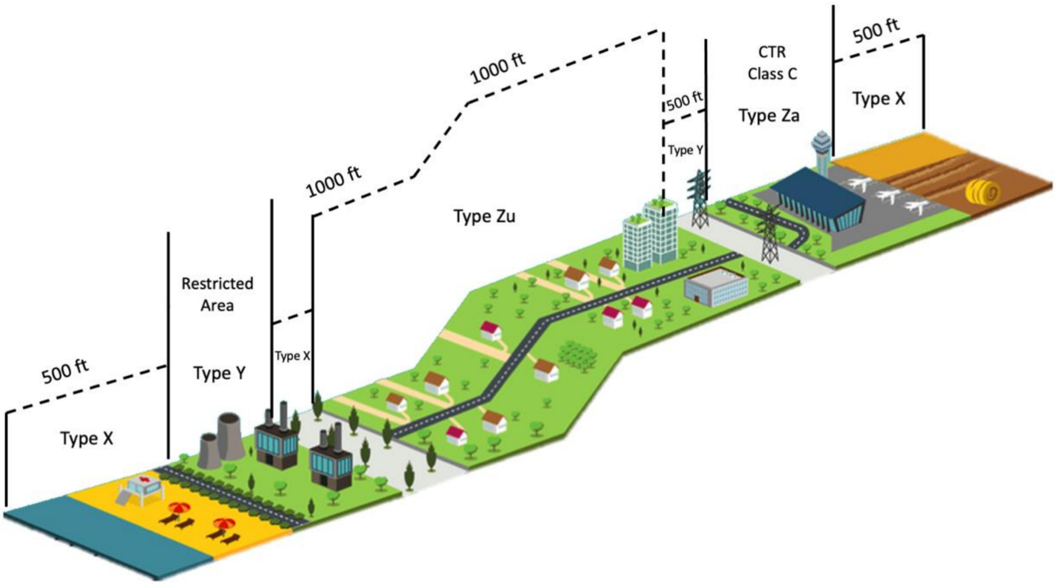

Figure 3. Classification of airspace adapted from the CORUS project [26]. The VLL airspace is divided into X, Y, Z volumes: X (low risk), Y (higher risk—access only with approved operation plan and specific technical requirements per volume) and Z (highest risk—access only with approved operation plan being Zu under U-space and Za the ATC controlled airspace).

Type Y airspace will be available from U2 and will facilitate VLOS, EVLOS (extended visual line of sight) and BVLOS flight. The risk mitigations provided by U-space mean that the Y airspace is more amenable to other flight modes than X.

Type Z airspace may be subdivided into Zu and Za, controlled by UTM and air traffic management (ATM), respectively. Za is simply a normal controlled airspace and is therefore immediately available. Zu airspace will be available from U3.

Because U-space provides more risk mitigations for Z type, it is more amenable to other flight modes, and allows higher density operations than Y airspace. Z allows VLOS and EVLOS and facilitates BVLOS and automatic drone flight.

Finally, EASA issued Opinion No 01/2020 [30] on 13 March 2020, which proposed a draft of the high-level regulatory framework for U space, closely linked to the two existing drone regulations [21,22]. The opinion proposed a first set of what were considered by EASA as the minimum necessary rules, which are to be complemented later with further provisions enabling a more mature state of airspace integration. The objective of the opinion was to create and harmonize the necessary conditions for manned and unmanned aircraft to operate safely in the U-space airspace focusing on strategic and pretactical traffic management techniques in order to mitigate the risk of collisions by requiring adapted services and sharing essential traffic information. In this sense, the opinion acknowledged that ensuring that U-space participants are cooperative is required until further development of detect and avoid (DAA) systems to ensure safe operations, in particular for BVLOS operations.

The airspace in which aircrafts fly can be classified as controlled airspace in which air traffic control (ATC) services such as clearance and traffic information. However, in uncontrolled airspace, there are no such services for manned aircraft. With the integration of U-Space in the future, when the member states designate a volume of airspace as U-space airspace, there will be a restriction: both for drone operators, to use U-space services to fly in that airspace; and for manned aircraft operators, to make available their position at regular intervals.

Based on the evaluation conducted by EASA of existing U-space services and their maturity, the following U-space services are considered necessary and mandatory to ensure safe and efficient operations in each U-space airspace implementation: network identification, geoawareness, traffic information, and drone flight authorization. In addition, member states may decide that additional U-space services are needed to support safe and efficient drone operations in specific volumes of U-space airspace implementation. They can decide to mandate them based on their risk assessment.

5. Results: Application of the European Drone Regulation to Mosquito Release Operations

This section will show the results of the application of the SORA methodology to the scenarios previously presented in Section 3.2: urban and rural scenarios. One of the main parameters for the application of the SORA analysis is the size of the drone. In both scenarios, a very small size drone is considered, with a characteristic dimension smaller than 1m or typical kinetic energy expected less than 700 J. In this category, drones with up to approximately 2 kg of weight can be included, which can have enough payload capacity and high endurance to perform mosquito release operations from the air according to the state of the art in Section 1. The release of mosquitoes from the drone does not require heavy systems to be integrated on the aircraft, nor do mosquitoes weigh too much, thus very small size drones are suitable. In the following, it should be noticed that for the characteristics of the drone and other parameters we consider ranges instead of particular values. The goal is to make the analysis broader and more useful to the drone community.

The SORA methodology is performed for each scenario, and the following subsections show the main results. In addition to that, a final overview of the conditions in the operation that could relax risks and mitigation measures is presented. Instead of showing the detailed steps of the SORA methodology, an added value of this paper is to summarize the main points. To this end, a division of the SORA into three fundamental parts is considered: evaluation of the GRC, evaluation of the ARC and the TMPR (tactical mitigation performance requirements), and final evaluation of the SAIL and identification of the OSOs.

5.1. Urban Scenario

Once the ConOps was defined in Section 3.2, it is possible to start with the application of the SORA methodology to analyze the level of risk of the operation, as well as to identify the mitigating measures to reach an acceptable risk in order to carry out the operation safely.

For the GRC evaluation, the drone is considered to fly over a controlled ground area. This means the ground area where the drone is operated and within which the operator can ensure that only the involved persons are present. In this way, taking into account the size considered for the drone, the resulting GRC is one. This is the lowest value of the GRC in the final evaluation table, so it is considered acceptable in this case. When controlling the ground area is not feasible, the GRC increases a lot since the case would turn to VLOS in a populated environment, resulting in a GRC of four. In this case, some mitigation measures should be applied to reduce this GRC, such as the integration of a parachute and the creation of ground risk buffers, which should both be approved by the authority through analysis and results.

Regarding the risk assessment in air, considering the type of VLL operation and in controlled airspace, an ARC-c is obtained. It is possible to apply both strategic and tactical mitigations to try to reduce that ARC level. First, strategic mitigations can be applied due to operational restrictions that may imply the geographical limitation of the volume in which the operation takes place or the temporal limitation to establish specific terms in which the operation is executed. It is also possible to establish strategic mitigation measures by establishing common structures and rules for all aircraft that will share such airspace. The last possibility is to apply tactical mitigations, which correspond to the measures that are applied once the aircraft is in flight, to reduce the risk of an encounter with another aircraft. This includes measures such as situational awareness through VLOS or alternative detect and avoid (DAA) systems.

According to [15], if the applicant considers that the assigned initial ARC is correct, which makes sense in this scenario, then that initial ARC becomes the final one, resulting in an ARC-c. This has implications at the level of the TMPR. In this scenario, the fact that the operation is VLOS is considered as an acceptable tactical mitigation for all levels of ARC. Despite this, the operator is advised to consider additional means to increase situational awareness of the air traffic operating in the vicinity. Additionally, the operator is required to have a conflict resolution scheme in which the applicant explains the methods used for detection and defines the criteria and decision-making in the case of possible encounters.

Once the GRC and ARC have been defined, it is possible to determine the SAIL associated with the operation. Taking into account the previous consideration, the result obtained is SAIL IV. This implies that the robustness levels required for the different OSOs are between medium (M) and high (H), meaning that the requirements that must be met in relation to the technical aspects of the drone and operation, operational procedures, pilot competencies, design, dependence on external systems such as GPS, human error, and operational conditions are moderately demanding and, in some cases, very demanding. This high level of SAIL is mainly because most cities have airports in their proximity and therefore are immersed in controlled airspace, which implies a high ARC and, therefore, a high SAIL. This also occurs for all levels of GRC less than or equal to 2, that is, for aircraft less than 25 kg, as can be seen in the SAIL allocation table shown in Table 2. Section 5.3 will show other alternatives for this kind of operation that offer more relaxed conditions.

Table 2. The SAIL determination table adapted from [24] is used to obtain the SAIL assigned to a particular ConOps.

	Residual ARC			
Final GRC	**a**	**b**	**c**	**d**
≤2	I	II	IV	VI
3	II	II	IV	VI
4	III	III	IV	VI
5	IV	IV	IV	VI
6	V	V	V	VI
7	VI	VI	VI	VI
>7	Category C operation			

This result comes from the formal application of the SORA to the ConOps described, with the result as analyzed being a fairly high SAIL for the reasons that have been discussed. However, it is possible to consider one of the STS published by EASA for this scenario, under which, as explained in Section 2, the regime is declarative by the operator and it is not necessary to have an operational authorization, which would greatly facilitate the operation in the regulatory aspect. The STS-01 scenario is the one that best fits the ConOps described, with the following characteristics: VLOS operation at a maximum height of 120 m, at a ground speed of less than 5 m/s, over controlled ground areas that can be in a populated environment, using drones with maximum weight up to 25 kg. Hence, the operator must declare that the conditions of its operation comply with the characteristics of STS-01.

The difference from the previous formal application of SORA is that in STS-01 the ARC level considered is ARC-b, which finally results in a much lower final SAIL (SAIL II). In order to consider this ARC-b, the airspace in which operations are intended to be conducted must have a low probability of the drone encountering manned aircraft or other airspace users. Even in urban areas with controlled airspace, as it is the analyzed airspace, this could be achieved by means of limiting the altitude of the operation (for example, fly always below the highest surrounding buildings) or following coordination procedures with ATC of the nearby airport/aerodrome. However, other restrictions imposed by the STS-01 definition are required, such as the control of the ground area from uninvolved people.

For this STS-01 it has been proposed that drones operating under this scenario should carry a C5 class mark. The main requirements that apply to class C5 drones are as follows.

- Be an aircraft other than a fixed-wing aircraft, with less than 25 kg of weight, which is the case considered in our analysis;
- Be equipped with a geo-awareness function;
- Provide to the remote pilot clear information about height of the drone above surface or take-off point;
- Limit the groundspeed to not more than 5 m/s;
- Limit the maximum height above take-off point or surface to 120 m;
- Provide means to the remote pilot to terminate the flight of the drone;
- Provide means to the remote pilot to monitor the quality of the command and control link, providing alerts in case of degradation or loss of communications.

Thus, by complying with the conditions described for STS-01, which fit very well with the ConOps described above, the operator could use this scenario and work under a declarative regime, which greatly speeds up all the bureaucracy associated with the operation in all aspects.

5.2. Rural Scenario

According to the ConOps presented in Section 3.2, for the assessment of the GRC, the drone is considered to fly over a sparsely populated area. This means that the flight is not executed over a populated environment and there is no need to control the presence of uninvolved persons in the area of operation of the drone. In this way, and taking into account the size considered for the drone, the resulting GRC is three. As in the previous case, it is possible to apply mitigating measures to reduce this GRC, such as integrating a parachute into the drone, but considering the SAIL determination table, there is not much difference between GRC 2 and 3 in terms of final SAIL, for levels of ARC-b or higher, so it is considered a nonessential mitigating measure.

As for the evaluation of the ARC in this scenario, considering the type of VLL operation and in noncontrolled airspace, an ARC-b is obtained. As in the previous case, tactical and strategic mitigation measures can be applied to try to reduce the level of ARC obtained. In this case, it is noted that lowering ARC-b to ARC-a is a complicated process, since the ARC-a level corresponds to an atypical or segregated airspace where the probability of encountering another aircraft is practically zero. Therefore, even if measures are applied to mitigate the risk of encounter in the air, the level of ARC-b is considered adequate for this scenario.

In this case, the evaluation of the TMPR is important because it is a BVLOS flight. Because the resulting ARC is ARC-b, the robustness level assignment for TMPR is low, as it is considered an airspace where the probability of encountering another aircraft is low but not negligible. Operations with a low TMPR level are supported by technology designed to help the pilot detect other traffic. This is where detect and avoid (DAA) systems come in, which can be based on ground systems, such as U-Space, or air systems such as the transponder called automatic dependent surveillance—broadcast (ADS-B) or the traffic awareness and collision avoidance system from FLARM (https://flarm.com/ (accessed on 1 December 2021)) for general aviation, light aircrafts, and drones. This ARC imposes low performance requirements for the DAA system; hence, in this case, the DAA system is required to detect approximately 50% of all possible aircrafts present in the operational volume in which an encounter could occur.

Having already obtained the final levels of GRC and ARC, it is possible to proceed with the determination of the SAIL. In this case, the resulting level is SAIL II, so it is an operation with lower risk levels than the case previously considered of the urban environment. This means that the robustness levels required for the different OSOs are low (L), and even many of them are optional (O). Certain objectives with a medium level of robustness (M) are appreciated corresponding mainly to operational procedures. As can be checked in

Table 2, for ARC-b, the SAIL level is II for GRC 3 and GRC 2, so drones with weight less than 25 kg can be considered with the same level of risk in this scenario.

5.3. Alternatives to Relax Risk Levels

Certain operational conditions can help relax risk levels and have less demanding mitigating measures. The environment in which the release of sterile mosquitoes is the most important is the urban scenario. At the same time, this scenario is the most complex due to the conditions that exist in this case: normally they are immersed in the airspaces affected by the nearby airports, they are populated environments with the presence of people on the ground, and there is more possibility of traffic from other aircraft (emergency, medical and police helicopters, etc.). However, it is important to note here that there is a current discussion between the different stakeholders on how to redefine and redistribute airspace. Currently, controlled airspace in urban areas covers most of the urban volume from ground to high altitude due to the proximity of their airports, so any drone that wants to fly in VLL would be in controlled airspace. That is why the drone and airspace community is studying relaxing the airspace distribution and starting from different heights depending on the distance to the airport, establishing a kind of cone to categorize the airspace.

According to the European drone regulation [14], drone operations can be included in the open category if they are considered low risk operations. The main characteristics of this kind of operation are that the drone should have a CE mark, weigh less than 25 kg and be operated in VLOS or assisted by an observer, and that the maximum height is 120 m. Today, the ASD-STAN organization has established a D05/WG08 working group called the UAS unmanned aircraft system, in which standardization activities are being developed for the definition of means of compliance to obtain the CE mark. Furthermore, there is one major restriction regarding the impossibility of carrying dangerous goods or dropping any material. This last aspect is crucial when it comes to discerning with the aviation authority the possibility of including this type of mosquito release operation in the open category. This must be further discussed with the aviation authority to reach an agreement.

By analyzing the different operational alternatives of the open category for mosquito release operations, options that include flights in urban environments will be highlighted. Within the subcategories into which the open category is divided, those particularities that affect the urban environment are as follow.

- Subcategory A1: The drone can fly in urban areas but not over an assembly of people and is trying to reduce overflying uninvolved persons. If uninvolved persons are overflown, the remote pilot must reduce as much as possible the time during which the drone overflies those persons. Apart from that, maximum take off weight (MTOW) of drones in this subcategory can be up to 900 g.
- Subcategory A2: The drone can fly in urban areas, but a safety distance of at least 30 m must be maintained with respect to the uninvolved people in the operation. In this case, the drone can weigh up to 4 kg.

The STS-01 standard scenario analyzed above in Section 5.1 is considered to be an extension of the A2 subcategory of the open category because of the similarities in the conditions and requirements that are posed. However, operations in an urban environment can fall under these two subcategories within the open category as long as they comply with the airspace restrictions imposed by the national civil aviation authority. This is the point that differentiates these subcategories from the STS-01 approach raised in Section 5.1, since most authorities reject the possibility of flying the open category in controlled airspace, in which most cities with nearby airports are immersed. Therefore, there is a current trend of redefinition of airspace in cities, which would allow the dimensions of these controlled spaces to be relaxed by not reaching the ground when there is a certain distance from the airport. This would allow flying in the open category in an urban environment under the criteria previously defined in most cities, as long as there is a certain distance from the aerodromes.

6. Discussion

This article presented the current legal framework in the EU for the use of drones as an innovative tool for the release of sterile mosquitoes within a SIT operational program against human disease transmitting mosquitoes in two different environments: urban and rural. Targeting urban environments for sterile mosquito release is a promising scenario due to the density of human populations. Additionally, drones are characterized by their ease of use and versatility of operation, and can significantly help release these mosquitoes in hard-to-reach areas and distribute them evenly over a given zone.

We analyzed the current European drone regulation and its impact on possible mosquito release operations. This regulation is based on the risk of the operation, and not in the weight of the drone, so it opens the possibility, for example, to fly drones in urban areas in the open category as explained in Section 5.3, which has been really complex until now. In addition, the SORA methodology proposed by the JARUS organization and accepted by the EASA authority within its auxiliary material to the regulations was described. SORA is a tool for analyzing the risks of drone operations, evaluating their level of safety, and identifying possible mitigating measures to achieve the desired level of safety. In addition, the concept of U-Space is introduced as a set of services that will help to manage drone air traffic.

Finally, the European regulation establishes common standards for all member states that will help harmonize and encourage the drone market. This new regulatory framework will affect all drone operations, including the release of sterile mosquitoes. As analyzed in this article, there are different alternatives for this operation that, depending on the risk of the operation, will fundamentally determine its classification in an open or specific category. Among the key criteria that determine this risk are drone weight, airspace classification (controlled or uncontrolled), operational scenario (presence of people or not), VLOS or BVLOS flight, flight height, etc.

Author Contributions: Individual contributions to this article are: "Section 1. Introduction", "Section 5. Application of the new European Drone regulation to mosquitoes-related operations" and "Section 6. Conclusions" by M.G.; "Section 2. New European Drone Regulation" by I.M., "Section 3. SORA Risk Analysis Methodology" by I.A., "Section 4. Integration into Airspace (U-Space)" by D.G., and A.O. and A.V. have contributed intensively by supporting and reviewing the article. In addition, M.G. has made the final compilation of the contents and I.M. has reviewed the document to give it coherence. All authors have read and agreed to the published version of the manuscript.

Funding: This work has been partially funded by the Spanish public organism CDTI through the iMOV3D R&D project (CER-20191007).

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Acknowledgments: The authors especially thank Antonio Jiménez for his support in the definition of the scenarios which are of interest for this application.

Conflicts of Interest: The authors declare no conflict of interest, and the funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

References

1. Tolle, M.A. Mosquito-borne Diseases. *Curr. Probl. Pediatr. Adolesc. Health Care* **2009**, *39*, 97–140. [CrossRef] [PubMed]
2. Ranson, H.; N'Guessan, R.; Lines, J.; Moiroux, N.; Nkuni, Z.; Corbel, V. Pyrethroid resistance in African anopheline mosquitoes: What are the implications for malaria control? *Trends Parasitol.* **2011**, *27*, 91–98. [CrossRef] [PubMed]
3. Hendrichs, J.; Vreysen, M.J.B.; Enkerlin, W.R.; Cayol, J.P. Strategic Options in Using Sterile Insects for Area-Wide Integrated Pest Management. In *Sterile Insect Technique*; Springer: Berlin/Heidelberg, Germany, 2005; pp. 563–600.
4. Dahmana, H.; Mediannikov, O. Mosquito-Borne Diseases Emergence/Resurgence and How to Effectively Control It Biologically. *Pathogens* **2020**, *9*, 310. [CrossRef] [PubMed]
5. Lowe, R.E.; Bailey, D.L.; Dame, D.A.; Savage, K.E.; Kaiser, P.E. Efficiency of Techniques for the Mass Release of Sterile Male *Anopheles albimanus* Wiedemann in El Salvador. *Am. J. Trop. Med. Hyg.* **1980**, *29*, 695–703. [CrossRef] [PubMed]

6. Bouyer, J.; Culbert, N.J.; Dicko, A.H.; Pacheco, M.G.; Virginio, J.; Pedrosa, M.C.; Garziera, L.; Pinto, A.T.M.; Klaptocz, A.; Germann, J.; et al. Field performance of sterile male mosquitoes released from an uncrewed aerial vehicle. *Sci. Robot.* **2020**, *5*, eaba6251. [CrossRef] [PubMed]
7. Ackerman, E. Drones make a special delivery-Mosquitoes [News]. *IEEE Spectr.* **2017**, *54*, 9–11. [CrossRef]
8. Chung, H.-N.; Rodriguez, S.D.; Gonzales, K.K.; Vulcan, J.; Cordova, J.J.; Mitra, S.; Adams, C.G.; Moses-Gonzales, N.; Tam, N.; Cluck, J.W.; et al. Toward Implementation of Mosquito Sterile Insect Technique: The Effect of Storage Conditions on Survival of Male *Aedes aegypti* Mosquitoes (Diptera: Culicidae) during Transport. *J. Insect Sci.* **2018**, *18*, 2. [CrossRef] [PubMed]
9. Zhang, D.; Xi, Z.; Li, Y.; Wang, X.; Yamada, H.; Qiu, J.; Liang, Y.; Zhang, M.; Wu, Y.; Zheng, X. Toward implementation of combined incompatible and sterile insect techniques for mosquito control: Optimized chilling conditions for handling *Aedes albopictus* male adults prior to release. *PLoS Negl. Trop. Dis.* **2020**, *14*, e0008561. [CrossRef] [PubMed]
10. Deaconu, A.M.; Udroiu, R.; Nanau, C.-Ş. Algorithms for Delivery of Data by Drones in an Isolated Area Divided into Squares. *Sensors* **2021**, *21*, 5472. [CrossRef] [PubMed]
11. Udroiu, R.; Deaconu, A.M.; Nanau, C.-Ş. Data Delivery in a Disaster or Quarantined Area Divided into Triangles Using DTN-Based Algorithms for Unmanned Aerial Vehicles. *Sensors* **2021**, *21*, 3572. [CrossRef] [PubMed]
12. Esch, E.D.; Horner, R.M.; Krompetz, D.C.; Moses-Gonzales, N.; Tesche, M.R.; Suckling, D.M. Operational parameters for the aerial release of sterile codling moths using an uncrewed aircraft system. *Insects* **2021**, *12*, 159. [CrossRef] [PubMed]
13. Lo, P.L.; Rogers, D.J.; Walker, J.T.S.; Abbott, B.H.; Vandervoet, T.F.; Kokeny, A.; Horner, R.M.; Suckling, D.M. Comparing Deliveries of Sterile Codling Moth (Lepidoptera: Tortricidae) by Two Types of Unmanned Aerial Systems and from the Ground. *J. Econ. Entomol.* **2021**, *114*, 1917–1926. [CrossRef] [PubMed]
14. OJEU. 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. *Off. J. Eur. Union L* **2018**, *212*, 1–122.
15. EASA. Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Part-UAS. UAS Operations in the "Open" and "Specific" Categories. 2019. Available online: https://www.easa.europa.eu/sites/default/files/dfu/AMC%20%26%20GM%20to%20Part-UAS%20%E2%80%94%20Issue%201.pdf (accessed on 1 December 2021).
16. Martinez, C.; Sanchez-Cuevas, P.J.; Gerasimou, S.; Bera, A.; Olivares-Mendez, M.A. SORA Methodology for Multi-UAS Airframe Inspections in an Airport. *Drones* **2021**, *5*, 141. [CrossRef]
17. Janik, P.; Zawistowski, M.; Fellner, R.; Zawistowski, G. Unmanned Aircraft Systems Risk Assessment Based on SORA for First Responders and Disaster Management. *Appl. Sci.* **2021**, *11*, 5364. [CrossRef]
18. Capitán, C.; Capitán, J.; Castaño, Á.R.; Ollero, A. Risk Assessment based on SORA Methodology for a UAS Media Production Application. In Proceedings of the 2019 International Conference on Unmanned Aircraft Systems (ICUAS), Atlanta, GA, USA, 11–14 June 2019; pp. 451–459.
19. Miles, T.; Suarez, B.; Kunzi, F.; Jackson, R. SORA Application to Large RPAS Flight Plans. In Proceedings of the 2019 IEEE/AIAA 38th Digital Avionics Systems Conference (DASC), San Diego, CA, USA, 8–12 September 2019.
20. OJEU. 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. *Off. J. Eur. Union L* **2008**, *79*, 1–49.
21. OJEU. Commission Delegated Regulation (EU) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems. *Off. J. Eur. Union L* **2019**, *152*, 1–40.
22. OJEU. Commission Implementing Regulation (EU) 2019/947 of 24 May 2019 on the rules and procedures for the operation of unmanned aircraft. *Off. J. Eur. Union L* **2019**, *152*, 45–71.
23. Agency EASA. Opinion No 01/2018: Introduction of a Regulatory Framework for the Operation of Unmanned Aircraft Systems in the 'Open' and 'Specific' Categories. 2018. Available online: https://www.easa.europa.eu/sites/default/files/dfu/Opinion%20No%2001-2018.pdf (accessed on 1 December 2021).
24. JARUS. JARUS Guidelines on Specific Operations Risk Assessment (SORA). 2019. Available online: http://jarus-rpas.org/sites/jarus-rpas.org/files/jar_doc_06_jarus_sora_v2.0.pdf (accessed on 1 December 2021).
25. SESAR JU. European Drones Outlook Study Unlocking the Value for Europe. 2016. Available online: https://www.sesarju.eu/sites/default/files/documents/reports/European_Drones_Outlook_Study_2016.pdf (accessed on 1 December 2021).
26. SESAR JU. U-Space Concept of Operations. 2019. Available online: https://www.sesarju.eu/sites/default/files/documents/u-space/CORUS%20ConOps%20vol2.pdf (accessed on 1 December 2021).
27. FAA. Unmanned Aircraft System (UAS) Traffic Management (UTM) Concept of Operations. 2020. Available online: https://www.faa.gov/uas/research_development/traffic_management/media/UTM_ConOps_v2.pdf (accessed on 1 December 2021).
28. GUTMA. UAS Traffic Management Architecture. 2017. Available online: https://www.gutma.org/docs/Global_UTM_Architecture_V1.pdf (accessed on 1 December 2021).
29. SESAR JU. U-Space Blueprint. 2017. Available online: https://www.sesarju.eu/sites/default/files/documents/reports/U-space%20Blueprint%20brochure%20final.PDF (accessed on 1 December 2021).
30. EASA. Opinion 01/2020: High-Level Regulatory Framework for the U-Space. 2020. Available online: https://www.easa.europa.eu/sites/default/files/dfu/Opinion%20No%2001-2020.pdf (accessed on 1 December 2021).