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Certification and safety aspects relating to the transport of passengers on high altitude balloons in Europe



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ABSTRACT

High-altitude balloons typically fly between 25 and 50 km in altitude, which, while below the Karman line of 100 km, is yet far above the altitudes typically flown by aircraft. For example, the highest-flying commercial aircraft – the Concorde – had a maximum cruising altitude of only 18 km. zero2infinity, a Spanish company, is currently developing a pressurized pod named “bloon” which will be capable of lifting six people, including two pilot crew members and four paying passengers, to an altitude of 36 km through the use of high-altitude balloons. The boundary between Airspace and Outer Space has never been legally defined, mostly because of the lack of activities taking place between the altitude where airplanes fly and the lowest orbiting spacecraft. High-altitude balloons do fly at these in-between altitudes and the prospect of commercializing access to these parts of the stratosphere poses some questions in a new light. Given the relatively low altitude at which they fly, it may well be that these types of balloons would be considered to operate exclusively within air space. However, given the technology involved in crewed high altitude balloon flights, which is more similar to spacecraft engineering than to traditional hot-air or gas ballooning, it is necessary to evaluate the various legal regimes, codes, and regulations that would apply to such flights, especially regarding licenses and liabilities. For high altitude balloon flights commencing in Europe, the European Aviation Safety Agency (EASA) would very likely be the competent certification or licensing agency for these flights, although there would likely be input from various national aviation authorities as well. However, because the European Commission (EC) has not yet issued regulations regarding commercial spaceflight, particularly the use of high altitude balloons, new rules and regulations governing such flights may still need to be drafted and promulgated. With the development of suborbital passenger vehicles such as bloon, Spaceplane as well as SpaceShipTwo (which is British-owned) this is clearly the appropriate time for the EC or other competent institutions to issue regulations regarding suborbital passenger flight. Rules and regulations regarding suborbital passenger transport such as liability and waivers to protect third parties, governments, and operators, need to be addressed by the European Union (EU) as a whole or at least by national or regional governments wishing to attract suborbital passenger flights to their territory. After all, it would be in Europe’s financial and other interests to create and foster a favorable legal and commercial environment for the aerospace business within the borders of the EU.

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1. Introduction

Human high-altitude balloon flights are not reserved to daredevils like Felix Baumgartner who completed the highest Space dive from a high-altitude balloon capsule for the Red Bull Stratos Project on October 14th, 2012. He was indeed the first human to fly with a balloon to these altitudes in 40 years, but in the 1960s before the rocketry race began, many manned high-altitude flights took place in Russia and the USA.

Balloonists were actually the first “astronauts” in the 1930s, if by astronauts we mean people that have seen the Earth from outside the boundary of our atmosphere. No need indeed to go up to 100km or more to be outside most of the mass of our atmosphere, or to see the view from Space as we imagine it: the black sky, the white sun, the blue line of the atmosphere and the curvature of the Earth clearly visible.

On November 12, 2012, zero2infinity, a Spanish company, launched an unmanned life-supporting capsule to 32 km from León, Spain, using a 43,000 m³ balloon and its own launch vehicle and ground equipment, thereby officially entering the small club of heavy balloon launch providers (Fig. 1).

Spain also has a heritage in human high-altitude ballooning. In 1935, Emilio Herrera, a Granada-born scientist and aviator, designed the first ever spaceflight suit, which he intended to use to fly to an altitude of 30 km with a balloon. He tested his suit in an airless chamber, and conducted many other experiments, until he was ready for flight with the balloon and the basket constructed. The start of the civil war in Spain abruptly halted the project. He went into exile and could never fly. The Apollo mission space suits design was based on that of Emilio Herrera. It may be symbolic but zero2infinity's founder comes from the same city and graduated from the same University as this Spanish Space pioneer (Fig. 2).

But why fly with humans? For the view, but not only. Several significant scientific discoveries were made by man-made observations from high-altitude platforms back in the beginning of the previous century, including cosmic rays, the effect of solar flares on humans in Space, water ice on the Martian poles, water vapor on Venus, etc, especially during Projects Strato-Lab and FATS0 (First Astronomical Telescopic and Spectrographic Observatory) with Audoin Dollfus in the 1950s–1960s [1].



Fig. 1. microballoon as seen at 32 km.

zero2infinity is not inventing anything fundamentally new but revisiting these historical capabilities in a 21st century fashion. Scientists and commercial passengers on our flights will not need to be test pilots, they will not need any particularly strenuous training, but they will get the benefits and the perspective from flying at these altitudes.

However, before these flights can take place commercially, safety and certification concerns need to be addressed. When thinking of safety and certification or licensing, several questions need to be answered: who is competent? Which regulations are in place? What are the safety systems and processes in place? How much experience exists in this field in general? How much experience does the company and its suppliers have?

2. Competence

The first concern is to identify the different competencies involved in the activity, in terms of applicable law, and competent organizations or authorities. This depends on several factors:

- Place where the activity takes place
- Nationality of the Operator
- International, European and national laws
- Other intergovernmental agreements, practices

2.1. Air or space?

High-altitude balloons typically fly between 25 and 50 km in altitude, which, while below the Karman line of 100 km, is yet far above the altitudes typically flown by aircraft. For example, the highest-flying plane – the Concorde – had a maximum cruising altitude of only 18 km. The boundary between Airspace and Outer Space has never been legally defined, mostly because of the lack of activities taking place between the altitude where airplanes fly and the lowest orbiting spacecraft. High-altitude balloons do fly at these in-between altitudes and the prospect of commercializing access to these parts of the stratosphere poses some questions in a new light. Given the relatively low altitude at which they fly, it may well be that these types of balloons would be considered to operate exclusively within air space. However, given the technology involved in crewed high altitude balloon flights, which is more similar to spacecraft engineering than to hot-air ballooning, it might also be considered that the environment is more Space-like than air-like.

Why does it matter? Aviation law and Space law are vastly different. The main difference is that airspace belongs to the State whose territory is located directly below, whereas Outer Space does not belong to any State [2]. However, in practical terms, the most important difference is the regime regarding licenses and liabilities. Space activities are considered more dangerous and the international liability regime in place is far more stringent. For any damage done by a Space object on the surface of the Earth or to an aircraft in flight, the liability of the



Fig. 2. Article about Emilio Herrera in 1936, USA.

launching State is absolute. Space law is State-centric and relies on States to be responsible, to control and to be liable for any Space activity on their territory or by their nationals [3,4].

Another main difference is the level of experience and reliability. Aviation is now part of everyday life, and while accidents are usually dramatic, the percentage of accidents is very low. Appropriate regimes and procedures are in place and traffic is well coordinated worldwide in order to avoid accidents.

Space activities, and especially private Space activities are new and regulated on a case-by-case basis. There is no international coordination, no international convention about e.g. liability ceilings, and nothing is yet in place to strictly evaluate the safety of commercial passengers during a space flight, mostly because of the lack of experience and the lack of standardization. Spaceflight is still very much an R&D sector, currently testing different means and technologies for improving efficiency, cost and safety.

While high-altitude ballooning is a sector with more years of experience compared to rockets, as it started with manned flights in the 1930s and is still going on today, and less dangerous in terms of technology, it is still very far from the level of experience of conventional airplanes or hot-air balloons. It is therefore necessary to evaluate the various legal regimes, codes, and regulations that would apply to such flights, especially regarding licenses and liabilities. As a starting point, it can be noted that there was a proposal to treat suborbital aeroplanes as aircraft by EASA employees: “Sub-orbital Aeroplanes generating aerodynamic lift during the atmospheric part of the flight are considered to be aircraft [...] EASA is therefore currently preparing to fulfill its role in relation to civil suborbital flights, aircraft and operations” [5].

Considering the mixed nature of high-altitude balloon activities, we believe that, here too, a pragmatic approach should be taken: the air law regime should be considered the primary regime, considering the altitude at which balloons operate, but adapted to the extreme altitude they operate in with elements of Space safety, especially

regarding components and some specific systems like environmental control and life support. That said, a recent development occurred when on September 26th, 2013, the Federal Aviation Administration (FAA) in the USA responded to a request from Paragon Space Development Corporation to determine which law applies to Paragon’s high-altitude balloon commercial space tourism vehicle, a recent project launched publicly at the same time. FAA concluded that, based on the fact that the manned capsule is built to operate in outer space, this type of operations will fall under Chapter 509 U.S.C. (commercial spaceflight).¹ This decision should be put into context. Paragon in this case was asking FAA specifically to include high-altitude ballooning into the commercial spaceflight regime. This is an understandable position in the US, as a temporary transitory regime has been put in place to foster the development of the new commercial spaceflight industry, with less stringent regulations than for civil aviation. In Europe, the regulatory context is quite different, and should the European authorities follow the same line as the FAA for this activity, it would have very different consequences on the industry. This will be further explained below in titles II.IV and V.

2.2. State of incorporation and operations

The State of incorporation and place of operations of the company is the other main factor for determining the competency over its activities. As a company incorporated in Spain and operating from Spain, zero2infinity is under Spanish and European jurisdiction. This means that it needs to follow first Spanish regulations, among others in terms of business law, export control and safety regulations. In some instances, Spain has delegated its competence to the European Union, and in other cases, international law may be applicable. This will be explained next.

¹ <http://www.worldviewexperience.com/FAA-Announcement.pdf>.

2.3. International, European and national laws

The Convention on International Civil Aviation (Chicago Convention, 1944 [6]) established the International Civil Aviation Organization (ICAO) and in its Article 1, recognizes the complete and exclusive sovereignty of each State over the airspace above its territory. This means that ICAO standards do not have direct force of law in the Contracting States, but that they need to be translated into national law.

In Europe, with the creation of the European Community, the Member States have progressively delegated their competence in the field of aviation safety to the Union. With the creation of the “Single European Sky”, this transfer is complete. Today, and as reinforced by the Treaty on the Functioning of the European Union (TFEU) in 2009 [7], the EU is competent for the development of common policies for all sectors of transport, including aviation, and its safety. In 2002, the European Union established the EASA, which is responsible within the European Union for regulating aviation safety, including airworthiness, air operations and flight crew licensing. This means that the EU Member States have entirely delegated this competence and are not allowed to establish additional regulations concerning aviation safety.

With the TFEU, a Space competence for the European Union was also introduced for the first time. Article 4.3 states that: “In the areas of research, technological development and space, the Union shall have competence to carry out activities, in particular to define and implement programmes”. Art. 189 assigns the drafting of a coherent Space policy to the Union.

This competence is however immediately restricted by the same articles: Article 4.3 continues to say: “however, the exercise of that competence shall not result in Member States being prevented from exercising theirs.” And Article 189 states in its paragraph 2 that “the European Parliament and the Council, acting in accordance with the ordinary legislative procedure, shall establish the necessary measures, which may take the form of a European space programme, excluding any harmonisation of the laws and regulations of the Member States.” This indicates a certain reluctance of the Member States to assign the Space competence entirely to the European Union.

In terms of competence, it makes the definition of an activity as submitted to Air or Space law quite important. The national State is solely and entirely responsible for its Space activities, whereas aviation safety is entirely in the hands of the European Union. Taking the pragmatic approach of submitting high-altitude balloons to an air law regime, this would mean that EASA would be competent to regulate this activity.

Specific regulations for high-altitude ballooning are non-existent within the EASA framework today. Existing regulations include the EC Regulation 216/2008 (“Basic Regulation”) [8], which outlines the essential requirements in civil aviation, its Implementing Rules, the EASA codes on Gas Balloons [9] and light aircraft [10], and the International Rules of the Air. These can serve as “certification basis” but need to be adapted through “Special Conditions”. New rules and regulations can be adopted to adapt the legal framework to the realities of the industry. EASA is

directly involved in the rule-shaping process. It assists the European Commission in its executive tasks by preparing draft regulations, and amendments thereof, for the implementation of the Basic Regulations, which are adopted as “Opinions”. It also adopts Certification Specifications, including Airworthiness Codes and Acceptable Means of Compliance and Guidance Material (AMC/GM) to be used in the certification process through Agency’s Decisions. When developing the rules and AMC/GM, the Agency is bound to follow a structured process as required by Article 52(1) of the Basic Regulation. Such process has been adopted by the Agency’s Management Board and is referred to as “The Rulemaking Procedure”. This procedure may include policies, which in this case would be a document offering guidance in order to develop the certification for manned high-altitude ballooning. According to Jean-Bruno Marciacq et al. [5], the absence of a certification specification or airworthiness codes applicable to a specific product does not prevent the airworthiness approval of the design of this particular product.

From ICAO, through EASA, one further level down is the national level. In certain cases, the European Union as well as EASA delegate competences to the national civil aviation authorities to regulate certain activities. EC Regulation 216/2008 states in its preamble: “It would not be appropriate to subject all aircraft to common rules, in particular aircraft that are of simple design or operate mainly on a local basis, and those that are home-built or particularly rare or only exist in a small number; such aircraft should therefore remain under the regulatory control of the Member States”.

It could be argued that, at least at the beginning of the activity, manned high-altitude balloon pods will only be manufactured in very limited numbers and be operated from the territory of one particular province or State, therefore potentially falling under the national authorities competency [11]. However, EASA has already expressed its interest in regulating this activity, and considering the potential growth of the activity, both in numbers of pods and in geographical locations, EASA recognition and certification would be a stronger basis for the operator. The local basis of the operations however requires EASA as well as the operator to also liaise with the national authorities and take their opinion into account.

2.4. Other practices

Further to international and national laws and regulations, other instruments may be applicable. Bilateral agreements between States or between agencies may exist to regulate specific activities. For example INTA (National Institute of Aerospace Technology) in Spain and NASA in the USA have signed a Memorandum of Understanding back in 1966 about the launch of sounding rockets for high-altitude experiments [11]. Should there not be any willingness of regulators in Spain or Europe to tackle the certification of manned high-altitude flights or suborbital flights, another possibility for the Spanish civil aviation authorities would be to enter into an agreement with the Federal Aviation Administration (FAA) in the US. In 1984, the US Commercial Space Launch Act [12] established the

basis for licensing and promoting commercial space flights in the US. This became the legal basis for FAA to regulate commercial human space flight. It created a now well-established Office of Commercial Space Transportation, responsible for issuing licenses for spaceports as well as space launch operators, and aiming at protecting the safety of uninvolved public on the ground, as well as flight crew and participants. It should be noted however that this FAA regime is temporary and should be revised as more experience is accumulated in the industry.

FAA can also license non-US nationals if there is no regulation in place in the State of the operator seeking a license. FAA has by far the most comprehensive regulatory body in place and operators as well as national authorities can take advantage of that.

One major difference between the EASA and the FAA approach needs to be mentioned at this point: The term “license” has a different meaning on each continent. When putting in place the competence of the FAA in terms of commercial space flight, the legislator was careful not to give the FAA the power to certify any commercial Space activities yet, but only the power to “license”. Certification in general means that the certifying authority guarantees that the activity is safe enough and takes full responsibility for this activity. This is especially relevant in the context of Space Law, where States are absolutely liable for any damage occurring on Earth as a result of Space activities. A license on the other hand specifically excludes any guarantee or responsibility on the side of the licensing authority. A license only concerns the operator, giving it the permission to carry out its activity for testing and research purposes, but without guaranteeing to the public that these operations are safe. This distinction is non-existent in Europe, and EC Regulation 216/2008 defines certification in its Article 3(e) as “any form of recognition that a product, part or appliance, organization or person complies with the applicable requirements including the provisions of this Regulation and its implementing rules, as well as the issuance of the relevant certificate attesting such compliance.” It goes on in Article 3(g) with: “certificate shall mean any approval, licence or other document issued as the result of the certification”.

The distinction between the two concepts is important in the US, as it gives a legal basis to commercial space flight activities, without guaranteeing the safety yet. This middle ground does not exist in Europe, and as such, does not foster the development of such activities.

3. Safety considerations

The fundamental objective of certification or licensing or any regulation of this type is to assure the safety of the public, the passengers and the flight crew. For commercial human high-altitude ballooning, many existing regulations can apply, and some need to be adapted to the specificities of the system.

3.1. Systems

Although manned Space balloons have existed before any other human space flight activities, they are one of the

least regulated form of space flight. The full system includes three main parts:

- the sail (balloon envelope)
- the pod (pressurized capsule)
- the descent system (including guided textile-based decelerators and an inflatable absorbing impact attenuation system)

To analyze the safety of a system, several aspects need to be taken into account:

- The intrinsic properties of the system: A balloon has no rocket propulsion system. When it is flying thanks only to helium, a non-flammable gas, there is zero risk of explosion. The rocket propulsion usually forms about 90% of the risk of space flight. The other substantial risk is related to high-speed reentry into the atmosphere. A balloon flight is never high-speed, and several redundant systems for slowing the descent makes the probability of catastrophic failure at this point very unlikely.
- The experience: Balloons have been flown before any other aircraft existed. High-altitude balloons have been flown with humans on board since the 1930s. Balloons are going to the stratosphere regularly with scientific payloads on board. The experience in high-altitude ballooning is quite extensive. The experience of the particular company operating the flights is important as well, and the number of test flights as well as the qualifications of the employees and key advisors are to be taken into account.
- The processes: Rigor in the design process, the choice of suppliers, the manufacturing and training of crew are essential and mostly company-specific.

Existing regulations for systems included in the above-described balloon system that need to be looked at are:

- Essential requirements for airworthiness (Annex 1 of the Basic Regulation EC 216/2008) [8]
- Certification Specifications for Free Gas Balloons (CS-31GB) [9]
- Certification Specifications for Normal, Utility, Aerobatic and Commuter Category Aeroplanes (CS-23) [10]
- Certification Specifications for Large Aeroplanes (CS-25) [13]
- FAA 14 CFR Part 460 Commercial Space Transportation—Human Space Flight Checklist [14]

The conventional way to certify a new aircraft or balloon is to look for the certification basis, find the system compliant to this basis and then issue a type-certificate. The first compliance that must be checked is the compliance with the Essential Requirements for airworthiness, which are the conditions to be fulfilled by a product, a person or an organization to ensure as much as possible that the public is not unduly affected by their operations or activities.

When identifying and designing rules for a new activity such as manned high-altitude balloons, the focus should

be on the safety objective rather than on the detailed design specification. Mitigating measures for risks should be proportionate to this safety objective. This seems to be the positioning of EASA when handling new and unconventional vehicles. The aim would be to ensure an equivalent level of safety as currently pertains to existing aeroplanes, as far as possible considering the inherent risks linked to new activities at the outer limit of our atmosphere [5].

Some systems are balloon and aviation-related, some are Space-related, it is possible to select relevant elements from different existing codes and regulations: some are the same as for suborbital planes, some are more related to balloons, some are to be found only in FAA or NASA rules. We will here detail some of the particular aspects of high-altitude ballooning systems that will need to be elaborated on during the certification process (this list is indicative, and by no means meant to be comprehensive).

- **retControllability and maneuverability:** This is an essential requirement as well as part of the CS-31 Regulation on Gas Balloons. Yet an open zero-pressure helium balloon is not precisely maneuvered by the pilot, but rather dependent on weather conditions. This risk is mitigated by precise trajectory calculations updated up until the time of flight, as well as the development of a guided parachute to allow for controllability of descent and landing.
- **Environmental control and life support systems:** Flying in the upper stratosphere makes it necessary to develop a closed-loop system, which can be found on vehicles like the International Space Station or submarines. ECLSS should comply with FAA 14 CFR 460.11 as there is no EASA regulation. This should satisfy the safety requirements to obtain permits to fly that allow Near-Space test flights within the EASA framework. The ECLSS shall monitor and control specific atmospheric conditions in the inhabited area: Composition of the atmosphere, including oxygen, carbon dioxide and any revitalization; pressure, temperature and humidity; contaminants including particulates and any harmful or hazardous concentrations of gases and/or vapors; ventilation and circulation. A redundant or secondary oxygen supply for the flight crew, a redundant means of providing cabin pressurization, as well as secondary systems to face a failure of the primary O₂ or CO₂ systems shall be included. Constant levels of pressure, temperature, humidity, O₂ and CO₂ concentration as well as hazardous gases and vapors shall be maintained and monitored to provide for a comfortable shirt-sleeve environment for the passengers.
- **Loads and safety factors:** the safety and load factors are defined in CS-31GB for conventional Gas Balloons. Whereas the load factors can generally be complied with, the safety factors especially for the envelope are unrealistic for such size balloons. All systems should be tested at least twice the nominal load. To define the specifics of this type of balloon safety requirements, it would be best to work together with experts in the manufacturing and use of these balloons, like the French Space Agency (CNES—Centre National d'Etudes Spatiales) for example.
- **Descent systems:** this is a non-existent part of the system in balloon or aviation standards. As the balloon will separate from the pod and textile-based decelerators will deploy, there needs to be at least a double redundancy to avoid catastrophic failure. The main parachute will also be pre-deployed on the flight chain, therefore avoiding the main risk related to parachutes: the non-deployment. The landing impact attenuation system shall absorb vertical and horizontal landing energy at ground contact under normal and emergency landing conditions. The maximum impact velocity should be 6 m/s and the maximum non-sustained deceleration 5 Gs. The maximum acceleration that passengers may encounter will only be encountered punctually and for a very limited time. A minimum of 20 cm ground clearance shall be provided to protect the pod and the crew of surface irregularities. The “sailing” on the ground needs to be prevented, by separating the descent system upon ground impact.
- **Flight abortion and escape systems:** Contrary to rocket or jet engine propulsion, helium is not flammable, and therefore is at lower risk for the occupants. Due to the size of the balloon, even if the envelope were perforated at altitude, this would only cause a slow descent, and always leaves the option of separating the balloon and descending nominally under parachute. In the case of depressurization of the capsule, emergency systems will be deployed like oxygen masks and systems to compensate the loss of internal pressure will be activated like pressurized bottles with O₂, air or N₂. In any case, the maximum altitude of 36 km and the possibility of separating the envelope also mean the redundant pressurization systems only need to function for a short time until the pod is at a low enough altitude.
- **Meteorological conditions:** For safe operations, wind conditions from ground up to 100 m at departure need to be below 4 m/s. Wind conditions at altitude should also be measured for trajectory calculations. The decision on launch/no launch needs to be taken in coordination with local civil aviation authorities, to ensure smooth coordination with air traffic, as well as safe launch and landing, away from populated areas, electrical cables and water (although the system is designed to allow for water landing) (Fig. 3).
- **Radiation:** Exposure to radiation in a high-altitude flight is higher than at sea level. This radiation environment is made up of radiation trapped in the Earth's magnetic field, galactic cosmic rays and solar particle events. This radiation is highly dependent on the latitude, the solar activity and the solar cycle. At these altitudes it is desirable and feasible to include a passive system to protect the occupants from this radiation. This can be achieved simply by adding a layer of material on the pod that does not let the rays through and acts as a radiation shield. However, even in the absence of such a layer, the dose received during a standard short duration high-altitude balloon flight is not higher than the dose received during a transoceanic air flight.



Fig. 3. microblloon during flight preparation.

- **Operations in reduced gravity:** During descent, a few moments of reduced gravity may be experienced. In order not to jeopardize the safety of the flight, all equipment shall be fastened and all fluids contained.
- **Instruments/avionics:** In addition to conventional aviation instruments, high-altitude flights need to be equipped with specific instruments that will function at these altitudes, like upgraded navigation and localization satellite systems, or radar altimeters. The Iridium satellite navigation system is one of the primary tools used.

3.2. Passengers

High-altitude scientific ballooning is a regular activity and not within the scope of civil aviation licensing. The main reason for this is that it does not involve passengers or crew and it usually takes place in remote areas by national Space agencies that develop their own internal regulations.

The only manned high-altitude balloon activities that have taken place until now where either scientific or military at the beginning of the previous century or within the realm of “extraordinary flights” such as test flights or exhibition flights (Red Bull Stratos test jumps and “Space Dive” on 14 October 2012). However, there is a major difference between permits to fly for test flights vs. flying with commercial passengers, and this represents a major hurdle for private spaceflight companies. Balloons are better positioned in this field compared to suborbital planes because there is no fundamentally new technology. All the equipment used is off-the-shelf commercial components, which have been tested and proven in flight numerous times.

The Essential Requirements state: “Cabin compartments must provide passengers with suitable transport conditions and adequate protection from any expected hazard arising in flight operations or resulting emergency situations, including fire, smoke, toxic gases and rapid decompression hazards. Provisions must be made to give occupants every reasonable chance of avoiding serious injury and quickly evacuating the aircraft and to protect them from the effect of the deceleration forces in the event

of an emergency landing on land or water. Clear and unambiguous signs or announcements must be provided, as necessary to instruct occupants in appropriate safe behavior and the location and correct use of safety equipment. Required safety equipment must be readily available.” According to the gas balloons code, passenger requirements on gas balloons are quite light, such as providing adapted restraints and handholds, and only providing separate compartments if there are more than six occupants.

All these provisions can be complied with, both thanks to system designs, and to training of the pilots. Considering the unusual flight profile and different experience provided to the passengers, a Near-Space flight shall include additional safety measures. For example, a safety briefing shall be provided to the passengers before the flight, as well as a basic medical check. Two pilots will be flying for four passengers to guarantee the well being of the passengers, as well as the safety of the others in case of panic attack. The pilots will have basic medical training.

3.3. Pilot training

Annex III of EC Regulation 216/2008 defined the Essential Requirements for pilot licensing. These have been detailed in the EC Regulation 1178/2011 [15] laying down technical requirements and administrative procedures related to civil aviation aircrew. Many of these can be applicable, such as pre-flight activities, technical and general vehicle knowledge, meteorology, navigation, communications, human performance and limitations, etc. However some may need to be adapted to the specifics of high-altitude flying, for example, specific wind knowledge, navigation by Space instrumentation only or technical knowledge of closed-loop environmental systems. On top of being a licensed gas balloon pilot, additional training may be valuable such as glider and parachute experience, parabolic flights, centrifuge tests for high G-loads, survival training for landing in remote areas, and simulation tools for getting used to the flight profile. The specific training and licensing requirements need to be defined together with ballooning experts and aviation authorities.

The main difference with conventional piloting is that in this case, the pilot has little control over the actual flight, and needs to communicate at all times with the ground, for flight paths updates and operational orders (envelope separation, parachute deployment and steering).

However, according to certification practice, the more training the flight crew has, the less stringent systems safety requirements need to be. The number of hours of experience the pilots shall have as well as the number of test flights required before taking commercial passengers need to be defined, in collaboration between the operator, experts and the authorities. All flight operations and emergency procedures shall be written and available in a Flight Manual on board. There needs to be a clear chain of command in the decision-making process and the execution of orders between the ground, the two pilots and the passengers.

The medical tests carried out on the pilots should be quite extensive both physically and psychologically.

Protocols for decompression sickness reduction, hard landings, ebullism, hypoxia and other injuries need to be formulated. The medical condition of the pilots need to be monitored before, during and after the flights, especially in the testing phase, in order to study and define the needs for the commercial phase. In the testing phase at least, the use of pressure suits is also required, although this might not remain a requirement for commercial operations, if the system is shown to be reliable enough (like on the ISS or on submarines).

4. Rulemaking process

As in every area of law, there are general rules and specific rules. Specific rules can be added on to the general rules in order to cater for the advent of a new field or a new activity. EASA has a specific procedure for rulemaking, which includes several phases, including a consultation between all member States and industry members for input. EASA published a Rulemaking Programme for a period of 4 years. This programme is built on the principle that the planning of the first year is a commitment and the planning for the following years might be subject to changes depending on changing priorities and availability of resources. Following this principle, the present 4-year Rulemaking Programme 2014–2017 commits the Agency to the rulemaking tasks planned for finalisation in 2014. The planning for the following years (2015–2017) is indicative and may be revised during the next planning cycle. High-altitude balloons are not yet included in the Rulemaking Programme, so what are the options?

While rulemaking may be the ultimate aim, the time may not be ripe for it yet. Making rules takes time and is also definite. It needs the activity to be well understood and tested. What usually precedes rulemaking is policy setting. According to Chatzipanagiotis [16], specific policy aims for private human spaceflight in Europe could be (a) the development of the private commercial human spaceflight industry, because of the advantages it can entail; (b) the promotion of safety, a principle governing any human activity; (c) the discouragement of irresponsible and reckless behaviour of the parties involved, for people should not be exposed to preventable risks; (d) the creation of a balance of interests between SFEs (Spaceflight Entities) and SFPs (Spaceflight Participants), in which, however, the fragile condition of the industry and the luxury nature of private commercial Space travel should be considered; and (e) the enhancement of legal certainty through unequivocal rules.

As these policy aims show, a balance needs to be achieved between protecting the safety of third parties and the necessary support to this new industry to test its activities and become proficient. This is effectively the way adopted by the FAA: according to Yates [17]: “After weighing several competing interests and policies to avoid artificial or rigid barriers that might stifle innovation unnecessarily, the regulations intentionally impose the least restrictive requirements that encourage safety. The development of the regulations reflects a model for cooperation between the industry and its regulating agency. In response, the industry has begun regulating itself and, where needed,

seeking formal laws to supplement its self-regulation.” The support encountered by zero2infinity from the national civil aviation authorities as well as from EASA is a good sign that this balance may be achieved in the coming years in Europe as well. For example, issuing experimental permits and permits to fly for test flights, both manned and unmanned is a first necessary step in order to achieve a better understanding of the actual needs of this nascent industry. The FAA has understood the need to support innovation in the realm of commercial spaceflight by granting licenses and experimental permits to worthy operators, complying with basic safety rules and processes. Safety is as much of interest to the third parties and to the regulators as it is to the operators themselves. One fatal accident, and the whole industry will be affected. Safety is in everyone's interest.

5. Liability considerations

The direct consequence of safety, or lack thereof, is liability. As was said previously, Space and Air regimes are different in this respect. Whereas under the Space law regime, the State is internationally liable for the activities of the operator, in Air law, the air carrier is directly liable towards the passengers.²

In the US, under the Commercial Space Launch Activities Act, “to obtain a license or permit, the operator must certify that it has informed the space flight participants of the risks of launch and reentry, including the safety record of the vehicle type; that the U.S. government has not certified the launch vehicle as safe for carrying humans; that the space flight participant has provided written, informed consent to participate; and that the operator has complied with FAA regulations”. The space flight participant must sign a waiver and an informed consent acknowledging that the participant understands the risks and that his or her presence on board the vehicle is voluntary. The waiver required in the Final Rule protects only the government, not the operator. For protection of the operator, a separate contractual waiver and release should accompany any informed consent. European authorities could also adopt this kind of transitory measure during the development and experimental phase of commercial spaceflight activities. This may however not be viable in the long term, as this type of waiver of responsibility for the State, as well as for the operator may violate public order and policy, as well as international air law and consumer laws, and may have no legal effect after the testing phase for an operating commercial business.

Apart from informed consent, another requirement both in Air and Space law is related to insurance. For example, New Mexico recently passed a law that waives the liability of the commercial spaceflight operator completely if there is no wrongful conduct. The informed consent form is deemed enough to say that the passenger is willing to take

² For more details about liability in Space law and how this would need to be adapted for Space tourism, see Freeland S., Fly me to the Moon: How will International Law cope with Commercial Space Tourism?, *Melbourne Journal of International Law*, Vol. 11, 2010, accessible at: <http://www.law.unimelb.edu.au/files/dmfile/download2f6a1.pdf>.

the risk. However the spaceflight operator is still obliged to take a 1 million US dollar insurance for this waiver to apply.

Obtaining insurance for a private spaceflight operator may prove difficult. In the case of zero2infinity, third-party liability insurance for the experimental unmanned phase has been obtained without major obstacle. With insurance, as with every aspect of the development of an unconventional activity, the spiral approach seems to be the most reliable, realistic and trustworthy. Starting with low-risk unmanned flights, building up experience and trust, learning how to work with civil aviation authorities, insurance companies, major suppliers, safety equipment... this is the most conservative approach to un-conservative activities, and is designed to build trust and safety for all parties involved, from the State to the public.

6. Value for Europe

Apart from some discussions between the experts in Europe on suborbital vehicles, Space law, aviation law and private commercial spaceflight, Europe has not tackled the subject of regulating this type of activity yet [18]. The time seems ripe to start doing so. Law and regulations are usually reactive, and adapt themselves to new activities that occur. Zero2infinity is not the only stakeholder currently looking to operate from Europe: Virgin is a British company and may want to open up the European market for SpaceShipTwo, EADS is planning the Spaceplane project. Other actors include: BOOSTER Space Industries, Orbispace, Dassault Aviation, Swiss Space Systems (S3), Space Expedition Corporation (SXC) and Spaceport Sweden. Concrete plans exist in Europe and it is important that legislators start thinking about providing a suitable legal framework. European Space Agency employees recognized this need and recommended in 2008 that “ESA should contribute in the development of a regulatory frame for space tourism in Europe, involving both civil aviation regulatory authorities and competent bodies from the EC, aiming also at a ‘more level playing field’ for all parties around the world, and supporting the interests of European industry” [19]. In October 2012 a workshop was held at the European Commission on “the Future Regulatory Framework for Suborbital Flights in Europe” as part of the FAST20XX project (Future high-Altitude high-Speed Transport 20XX, 2009–2012). In 2011, the European Commission asked EASA whether they could set up an optional lighter regime, much like the US licensing approach. The resulting internal analysis concluded that this is possible, but that it would require modification of EASA’s Basic Regulation, and implementation would be in the hands of the Member States. EASA would be in principle ready to provide its services in the field of suborbital flight, if a mandate to that extent and the corresponding resources are provided [20].

Europe’s advantage in this field could be vast if the legal and regulatory framework would be more welcoming. Europe could be particularly competitive, thanks to being an ITAR free zone with many other attractive tourism opportunities. The Eurozone is a very attractive and varied destination, easy to access from all over the world, with many competent, innovative and dynamic entrepreneurs, looking to create jobs, strengthen the

competitiveness of Europe and redefine its image as a source of innovation, technology and openness. To counter the length of bureaucratic procedures, the way forward needs to be opened by the operators themselves by creating the case for real business in Space and a safe and sound approach to Near-Space and Space travel, convincing the authorities that this can be done and that the benefits outweigh the risks. It is primarily the responsibility of the operators to provide precedents that create trust and a safe environment for this pioneering activity. Regulations, insurances, licenses and certification will follow.

7. Conclusion

The objective of the paper was to study the following question: How to operate safely and in compliance with existing regulations, a commercial high-altitude balloon program that includes the transport of passengers in Europe? The answer seems to be found in many different documents, across continents and with an important aspect of common sense and self-interest. A regulation per se is non-existent, be it in the USA or in Europe, but after almost a century of experience, safety must be achievable by applying the lessons learned of the past and making one’s own experience. In pioneering fields like this one, a certain amount of collaboration between stakeholders as well as openness and abundance by essential safety rules should allow the achievement of the common goal: create a new industry with all the economical and technology benefits that this entails, while guaranteeing the safety of the public.

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