



PRELIMINARY REGULATORY IMPACT ASSESSMENT

Task Nr: 21.046
Title: Replacement parts
Date: 06 March 2009

1. Purpose

a. Issue which the NPA is intended to address:

The vast majority of non-TC holder replacement parts in the world are produced in the US under the Parts Manufacturer Approval (PMA). This might be the result of a difference in regulatory or certification procedural burden on the manufacturers of replacement parts. It might also be the result of misunderstanding of the EASA rules or it may have just historical reasons.

The processes used for the design approval of replacement or modification parts are indeed different in Part 21 and FAR 21, mainly due to the basic principles that were used to draft JAR-21, and which are still valid in Part-21. These principles are:

- Clear separation of regulations dealing with design and production
- Demonstration of design capability required, except for minor design changes
- Required link with TC Holders for applicants proposing major design changes, when they need the support of the TC Holders to get design or certification data.
- a replacement part designed by someone who is not the TC holder is considered a change to the design even if it is identical to the original part.

These EU conditions seem to be more demanding than the equivalent US regulations. In addition, the respective role and involvement of EASA and FAA are different.

Approval of parts and appliances in Regulation (EC) 1702/2003 Part 21

The approval of parts and appliances is split into a production approval and a design approval:

Production

To be able to release parts and appliances after production with an EASA Form 1, which is a condition for installation in European type certificated aircraft, the production organisation must hold a Production Organisation Approval (POA) in accordance with Subpart G¹.

Design

Part 21A.303 provides for three possibilities to approve the design of parts and appliances:

- a) as part of a TC, change to TC or STC in accordance with Subparts B, D or E;
- b) ETSO authorisation (only for parts for which there is an ETSO standard)
- c) Standard Parts in accordance with officially recognised standards.

For designing replacement parts only option a) is relevant; and more specifically the Subpart D and E provisions of Part 21.

¹ In theory a Subpart F Letter of Agreement would also be possible but this is not very likely for production of large numbers, which is normally the case for parts and appliances

There are two possibilities to obtain design approval of parts and appliances designed by someone who is not the TC holder.

Replacement or modification parts corresponding to a **minor** change in design may be approved as minor changes under Part 21A.95. In such case:

- There are no conditions on the applicant (with regard to demonstration of capability)
- There is no need for a link with the TC holder.
- Compliance will have to be shown with the applicable CS provisions as required by 21A.101. For minor changes these specifications are those included in the certification basis of the concerned product.

Replacement or modification parts corresponding to a **major** change in design shall be approved as a Supplemental Type Certificate under Subpart E. In such case:

- The applicant must hold a Design Organisation Approval (DOA) or obtain agreement for alternative procedures to DOA.
- An arrangement with the TC holder is normally required unless the applicant can show that the basic design information is adequate from his own resources.
- Compliance will have to be shown with the applicable CS provisions as required by 21A.101. For significant major changes these specifications are normally the latest ones, however, it is assumed that replacement parts will normally correspond to a non-significant change in which case the applicable specifications are those included in the certification basis of the concerned product.

In the case where parts are not designed by the TC holder, there is an additional requirement to mark those parts with the letters EPA (European Part Approval).

Approval of parts and appliances in the US

For the manufacturing of replacement parts and appliances the FAA can issue a separate stand alone approval: Parts Manufacturing Approval (PMA).

The FAR 21.303 "Replacement and modification parts" allows three methods for design approval:

- Test and computation showing that the design of the part meets the applicable airworthiness requirements;
- Showing that the design of the part is identical to the design of the part being replaced; or
- Design obtained under a licensing agreement.

For the production a "fabrication inspection system" is required which is comparable to the EASA Part-21 Subpart F "production without production organisation approval". It can be seen as a quality system without quality assurance and without quality management.

A general concern voiced as regards the US PMA system is that the design approval method does not sufficiently assure that products with PMA parts installed fully comply with the airworthiness requirements.

Below is a crude comparison of the European system with the US PMA system.

EASA (EPA)	FAA (PMA)
No separate approval	Self contained approval including design and production
Compliance showing with	acceptance of "identicality", or

applicable CS	"test and computation"
POA mandatory	"fabrication inspection system" (comparable to our Subpart F)
For "major": need to show design capability	no need to show design capability
For "major": Link with TC holder or adequate own resources	No link with TC

In October 2006 the FAA issued an NPRM to FAR 21 in which the production requirements for PMA manufacturers are strengthened to be consistent with those for TC holders. If adopted, this will eliminate one of the differences between Europe and US.

Intended EASA study

The Agency has endeavoured to launch a study on the various aspects of replacement parts manufacture, notably to compare the regulatory systems of the US and the EU, to investigate the practical way PMA parts are approved in the US and to produce statistical data on the use of PMA parts and the safety of those parts. Unfortunately, even after a repeated call for tender, we have not been able to find a suitable candidate for conducting the study.

EASA rulemaking plans:

In this context, the Agency decided to initiate a rulemaking activity on the manufacture of replacement parts, with the view to adapt it as much as possible to eliminate the perceived handicap of the European Industry, without affecting the safety of the products on which they are installed.

The Agency has learned recently that the FAA has planned a rulemaking task in which it is intended to strengthen the requirements applicable to the design approval of PMA parts. The Agency will discuss with FAA how we could cooperate on this rulemaking activity.

b. Scale of the issue:

Major

According to the FAA the PMA parts market represents 5% of the total parts market in the US. For Europe this is estimated to be between 3 and 4 % of the parts market².

PMA parts sales worldwide represented around \$330 M in the year 2005 (excluding PMA under license)³. It was estimated at \$360 M in 2006 out of which 33 % was sold in Europe. The worldwide sales are envisaged to grow to \$700 M in 2010⁴.

c. Brief statement of the objectives of the NPA:

The objective of the rulemaking task is to create balance between the conditions for PMA approval in the US and the rules for designing and producing replacement parts in the EU.

2. Intended Effects

Amend or clarify the rules for design and manufacture of replacement parts, with the view to eliminate as much as possible the perceived handicap of the European Industry, without affecting the safety of the products on which they are installed.

² Based on the figures on the distribution of the market of a major PMA manufacturer

³ Source: AeroStrategy

⁴ Source: The Engine Yearbook 2008, Aviation Industry Press.

3. Options

a. The options identified

1. Do nothing.
2. Copy the FAR-21 provisions for PMA into Part-21. Introduction of an approval which would cover the design and production of replacement parts.
3. Create in Part 21 a new design approval for replacement parts similar to PMA but with approval requirements proportionate to the safety risk of the particular part, and keeping the production approval separate.

Currently there is no dedicated design approval process for replacement parts, which means that designers of replacement parts must use the requirements for changes to design. Since a replacement part, which is identical to the original part cannot be considered a change in the design, the use of the change approval requirements might not be considered appropriate. The requirements for issuing such dedicated approval could be tailored to the specificities of replacement part design. For example there would be no need to classify in minor and major, but instead only in critical or non-critical. In general the weight of the approval procedures should be commensurate to the possible impact on safety. Applying this principle may allow some alleviation to the approval requirements as currently used for the approval of changes.

4. Develop guidance material on how existing requirements in Part 21 can be used to design and produce replacement parts.

The current interpretation of Part 21 is that the design of replacement parts can be approved either as a minor change or as an STC. However these provisions are not used today for this purpose. This may be the result of insufficient guidance explaining how these requirements can be used for the purpose of designing and producing replacement parts.

b. The preferred option selected:

See under 6c "final assessment".

4. Sectors and stakeholders affected

Manufacturers of aviation products and parts and the users of those parts: operators and maintenance organisations.

5. Impacts

a. All identified impacts:

i. Safety

Option 1: this is the zero option; the basis for comparison.

Option 2: A general concern voiced as regards the US PMA system is that the design approval method does not sufficiently assure that products with PMA parts installed fully comply with the airworthiness requirements. However, statistical evidence that PMA parts are less safe than original parts is not available. The two approval methods available would be by showing that the part meets the relevant airworthiness specifications through test and computation or by showing that the design of the replacement part is identical to the original part. The first method should lead to the same safety of the replacement part as of the original because the same requirements are applicable. The result of the second method is uncertain because EASA has no experience with this method and there is insufficient statistical data about the US experience to prove that this method leads to equally safe parts. When assessing safety, uncertainty is equal to an unknown risk and is normally not acceptable.

Option 3: The approval requirements would be commensurate to the safety risk of the particular part. The production requirements are those that are also applicable to

original parts. With these two principles the safety impact compared to the zero option should be neutral. However it is not entirely clear how this could be achieved.

Option 4: The requirements will remain unchanged but the use of existing regulatory provisions for the purpose of designing and producing replacement parts is promoted. Therefore no impact on safety is expected.

ii. Economic

All of the options 2, 3 and 4 are expected to increase the European market share of parts manufacturing by promoting the design and production of replacement parts by entities other than the TC holder. The highest numbers can be expected for option 2, slightly less for option 3 and the least for option 4. In all cases this will lead to a slight shift of income related to the sales of spare parts from the original manufacturer to other players in the market. Experience has shown that prices of PMA parts are lower than the price of original parts so the overall costs of spare parts for the operators are expected to decrease. So the overall economic impact is considered positive.

iii. Environmental

No environmental impact is expected.

iv. Social

Although there may be a shift of labour from the TC holders to the replacement part producers, no significant social impact is expected.

It is also expected that the increased activity in Europe would eliminate this shift of activity and actually boost employment in Europe. Again the biggest impact would result from option 2 and the smallest from option 4.

v. Other aviation requirements outside EASA scope

Giving better opportunities for more different companies to enter a certain market is in line with the principles of a free market.

vi. Foreign comparable regulatory requirements

Option 2 will bring full harmonisation with the US rules. Option 3 will bring EU rules closer to the US rules. Option 1 and 4 will not add to harmonisation of rules.

b. Equity and fairness in terms of distribution of positive and negative impacts among concerned sectors:

Options 2, 3 and 4 may lead to a shift of work from the TC holders to other producers of aviation parts. The costs for this shift are borne by the TC holders and their suppliers. The new actors in this market will benefit as well as the users of the parts: the operators and maintenance organisations.

6. Summary and Final Assessment

a. Comparison of the positive and negative impacts for each option evaluated:

Option 2 will bring the biggest economic benefit and will bring full harmonisation with the US. It will thus contribute to restoring the balance in the replacement parts market. However the safety impact is partly uncertain and will thus introduce a safety risk.

Option 3 will have a positive economic impact and is intended to have a neutral impact on safety. Until the detailed rules are established and implemented there is an uncertainty about the safety level that is actually going to be achieved.

Option 4 is expected to have a slight positive economic impact and will also have no impact on safety.

b. A summary describing who would be affected by these impacts and analysing issues of equity and fairness:

The positive economic impact from options 2, 3 and 4 will be of benefit to organisations that will newly enter into the replacement parts market and also to the end users of replacement parts; the operators and maintenance organisations.

c. Final assessment and recommendation of a preferred option:

Based on the above assessment the Agency envisages to further developing option 4, with a possible use of option 3 in the future if option 4 does not achieve the objective of this task.

References

- Regulation (EC) No 1702/2003; Part-21
- FAA Part-21
- The Engine Yearbook 2008, Aviation Industry Press.