



Economic Commission for Europe**Inland Transport Committee****Working Party on the Transport of Perishable Foodstuffs****Seventy-first session**

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Item 5 (b) of the provisional agenda

Proposals of amendments to ATP: New proposals**Audit reference document for manufacturers of temperature-controlled transport equipment****Transmitted by the Government of France****Background**

1. The Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage (ATP), signed in 1970, is based on the competent authorities designated by the contracting parties issuing certificates of technical compliance.

2. Annex 1, Appendix 1, paragraphs 6 (a) and 6 (b), of ATP state that new equipment of a specific type serially produced may be approved by testing one unit of that type, and that the competent authority shall take steps to verify that production of other units is in conformity with the approved type. For this purpose it may check by testing sample units drawn at random from the production series.

3. Several signatory States certify manufacturers of temperature-controlled transport equipment for which certificates of compliance are required in line with ATP. This modern approach is preferable to the more expensive and less flexible routine checks of equipment but, although a manufacturer's audit is a permitted alternative to checking of sample units, the procedure for such an audit is not specified and should be laid down to ensure that the competent authorities use standard practices.

4. France has had certification arrangements for persons applying for certificates for new equipment, on the one hand, and for ATP experts applying for renewal of certification, on the other, for more than 10 years. These certification arrangements are regulated by audit reference documents that form part of the French regulations. The reference documents were drawn up under the aegis of the Ministry of Food, which is responsible for the implementation of ATP in France, with the participation of all stakeholders: body manufacturers, unit manufacturers, transporters, hire companies, ATP experts, ATP testing stations and the ATP competent authority.



5. Since no framework for the audits is given in ATP, the audit reference documents used vary in their degree of detail and between countries or even between operators in some countries that have set up several operators. Hence there may be variations in the application of ATP and the requirements between signatory countries. It would thus seem necessary to standardize the certification arrangements, as France has already requested.

Proposal

6. France therefore proposes the following amendment to ATP which:
- States explicitly that such audits, based on a standardized reference document, may be used as an alternative to the testing of units drawn at random from the production series; and
 - Describes the criteria for a manufacturer's audit, on the other;

to meet the requirements of Annex 1, Appendix 1, paragraph 6 (b).

Impact

7. The introduction of an audit of the manufacturer's quality system into uniformity assessment methods is already common practice among competent authorities, specifically in France, Germany and Italy. The adoption of a common audit reference document would help to standardize practices and provide a technically sound basis for audit results, giving them a degree of recognition.

8. By standardizing practices, such arrangements would reduce the adaptation costs for manufacturers who are very often working at international level, marketing their products in several ATP signatory countries. The cost of the audit arrangements is less than that of routine checks of equipment. Lastly, many manufacturers have already been audited. The economic impact of the procedure would thus be generally positive.

Proposed amendment to ATP

9. It is proposed to add the text in bold below to Annex 1, Appendix 1, paragraph 6 (b):

“(b) The competent authority shall take steps to verify that production of other units is in conformity with the approved type. For this purpose it may check by testing sample units drawn at random from the production series **or carry out audits of production on the basis of the reference document given in annex 4;**”

10. It is proposed to add an Annex 4 to ATP on the basis of the following proposal:

Annex 4

Audit reference document for manufacturers of controlled-temperature transport equipment

Detailed requirements

Clauses of NF EN ISO 9001:2008

Requirements for manufacturers, companies responsible for the reconditioning or thermal re-insulation of equipment for the carriage of perishable foodstuffs and agents applying for certification

1. Scope

1.1 General

1.2 Application

Scope and application

This reference document applies to any company involved in the manufacture of temperature-controlled transport equipment for professional use in respect of which a certificate of technical compliance is being applied for. This includes:

- Manufacturers of units (bodies, tanks, etc.);
- Manufacturers or fitters of insulating systems on existing units (tanks or bodies);
- Manufacturers of thermal appliances (refrigeration units, eutectic plates, gels, dry ice, etc.);
- Manufacturers of packaging for temperature-controlled carriage (cardboard boxes, envelopes, crates, coolers, flexible/rigid, disposable/reusable appliances, etc.) of any size;
- Manufacturers of insulated containers less than 2 cubic meters in size, which may or may not be fitted with a thermal appliance;
- Fitters of thermal appliances on transport equipment;
- Thermal appliance commissioning operators;
- Companies responsible for the reconditioning of mechanically refrigerated equipment;
- Companies responsible for the thermal re-insulation of insulated or mechanically refrigerated tanks;
- Manufacturers of marine containers used in the context of ATP.

This reference document is intended for both single-site and multi-site companies and, where appropriate, their suppliers. All production or business units of a company in its activity are concerned by this reference document. Likewise, when a company has several facilities providing

the same services, each site is expected to apply the terms of this reference document.

Hereafter, to facilitate the reading of the document, the term “manufacturer” will be used as a generic term to designate a company as described above. Likewise, the term “thermal appliance” describes any appliance which produces cold or heat.

Exclusions

Where exclusions are provided for in the chapters of ISO 9001: 2008, compliance with this reference document is established only if these exclusions are limited to the requirements of clause 7.3 (design and development) and do not affect the company’s ability, nor release it from its responsibility, to manufacture equipment in compliance with the certified type and the applicable regulatory requirements.

Possible adaptations

Regarding openings, the following are deemed to be adaptations of equipment in which the type has been subjected to an official test report in one of the testing stations signatory to ATP:

- Equipment meeting the requirements in Table 1 of this document.

Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage (ATP)

NF EN ISO 9001: 2008: quality management systems — requirements

See ATP, Annex 1.

The manufacturer must have a valid authorization contract with the competent authority defining the respective roles and responsibilities of the manufacturer in respect of the applications for certificates that are made.

The company shall have:

- Documentation relating to the materials and the equipment used to produce them and, in particular, documentation relating to insulating materials;
- The above-mentioned standards and reference texts, which are mandatorily applied;

2. Normative references

3. Terms and definitions

4. Quality management system

4.1. General requirements

4.2. Documentation requirements

4.2.1. General

4.2.2. Quality manual	<ul style="list-style-type: none">• The present reference document. <p>The company shall maintain a quality manual and incorporate in its scope compliance with the requirements of this reference document, with all prevailing regulatory texts on the temperature-controlled carriage of perishable foodstuffs and particularly with ATP.</p> <p>If the scope of the company's quality system is not limited to the production of equipment governed by the regulatory texts, the description of the interactions between the system processes should enable the processes related to such equipment to be easily identified.</p>
4.2.3. Control of documents	<p>Documents which define equipment or a sub-assembly, such as drawings, diagrams making up the technical documentation, as approved by an official station which has issued an official test report, ensure compliance with the certified type.</p>
4.2.4. Control of records	<p>Without prejudice to compliance with the regulatory provisions and obligations toward the competent authority, the company shall define a policy and a procedure relating to the changes in the equipment definition documents which may affect the regulatory characteristics and/or the thermal performance and/or integrity of the equipment type. Such changes shall be notified in a timely fashion to the competent authority when such changes are not covered by the adaptations table in Annex 1 of this document.</p> <p>Any change which has not been notified to, or approved in writing by, the manufacturer and which may affect the regulatory characteristics of the equipment, is the responsibility of the equipment owner and not that of the manufacturer.</p> <p>The records of processes establishing compliance of the manufactured equipment to the type subjected to an official test report and to the relevant provisions shall be described in the quality documents and their method of archiving shall be defined.</p> <p>Such archiving shall allow rapid and safe identification of the compliance checks conducted on equipment marketed within the past two years, and the results and sanctions of such checks.</p>

The qualification folders for software and data transfers shall be included in the controlled records.

If records have been made in electronic form, the software and data transfers relating to such records shall be qualified under the responsibility of the manufacturer. The records relating to quality shall be maintained for at least a year; they shall be kept from one authorization audit to the next.

The technical files for each equipment shall be kept for at least 13 years (12 years + 1 year) after the initial marking date.

5. Management responsibility

Management shall ensure that the products are compliant and this reference document is complied with, and shall monitor any modifications to it on a regular basis.

5.1. *Management commitment*

Management shall use only the test reports which relate to its own certified type. Otherwise, prior to production, management shall seek to obtain the positive opinion of competent authority, based on a folder which includes:

5.2. *Customer focus*

- An original written authorization from the owner of the test report(s)

5.3. *Quality policy*

- Any element justifying that the manufacturing process being contemplated is the same as that implemented for the certified type which is the subject of the test report in question, particularly, where appropriate, in regard to gluing, panel assembly, connection to chassis, and final inspection.

5.4. *Planning*

Management shall inform the competent authority, in writing, of any change affecting its activity as subjected to this reference document.

5.4.1. Quality objectives

5.4.2. Quality management system planning

5.5. *Responsibility, authority and communication*

Management shall apply for certificates in a sincere and true manner.

5.5.1. Responsibility and authority

5.5.2. Management representative

5.5.3. Internal communication

5.6. *Management review*

It shall supply the competent authority of whatever type with information which is correct and has been checked. The act, by a manufacturer or professional subject to the regulation or its agent, of submitting an application for an equipment certificate to the competent authority constitutes a declaration of conformity of that equipment to the applicable regulatory requirements and to the requirements contained in this reference document.

5.6.1. General

5.6.2. Review input

5.6.3. Review output

Management shall implement a system for tracking and monitoring the products and services of its suppliers that are not certified on the basis of this reference document (see § 7.4).

For agents applying for certification, management is responsible for the correct distribution of the information transferred to the relevant competent authority.

Management shall not subcontract the certificate application.

The administrative authorities in charge of the applicable regulation, the official testing station and the competent authority are to be considered to be “clients”.

A management representative is responsible for the definition and tracking of the ATP certificate application processes. The procedures describing these processes must be approved by the competent authority and may not be modified without its prior consent.

The same person, identified by name, must be appointed to be responsible for routine relations with the services in charge of applying the regulations (central administration and local State services, competent authority, etc.).

The manufacturer shall ensure that the resources required for achieving the regulatory compliance of the equipment are available at all times.

The manufacturer’s personnel shall be aware of the regulatory requirements applicable to the equipment. The manufacturer shall describe the skills and authorization management system it deems necessary to implement in order to ensure the compliance of the equipment.

The personnel in charge of checking the ATP compliance of the equipment shall, at their own level of control, have particular understanding of:

- The regulatory requirements applicable to the equipment and its inspection;
- The inspection and verification procedures.

The personnel shall be technically skilled (records of initial and continuing training, and of qualifications).

The persons who formulate the certificate

6. Resource management**6.1. *Provision of resources*****6.2. *Human resources***

6.2.1. General

6.2.2. Competence, training and awareness

6.3. *Infrastructure***6.4. *Work environment***

7. Product realization**7.1. *Planning of product realization*****7.2. *Customer-related processes***

- 7.2.1. Determination of requirements related to the product
- 7.2.2. Review of requirements related to the product
- 7.2.3. Customer communication

7.3. *Design and development*

- 7.3.1. Design and development planning
- 7.3.2. Design and development inputs
- 7.3.3. Design and development outputs
- 7.3.4. Design and development review
- 7.3.5. Design and development verification
- 7.3.6. Design and development validation
- 7.3.7. Control of design and development changes

applications to the competent authority shall be qualified and authorized by the manufacturer. These persons shall have a job sheet which specifies their duties regarding certificate applications and subsequent responsibilities.

The agent shall have an updated list of the persons authorized to apply for certificates of technical compliance.

Where infrastructure characteristics affect the performance, monitoring or measurement of the product, these characteristics shall be controlled (infrastructure qualification) and the relevant records formalized.

The regulations applicable to equipment, any amendments thereto, the procedures for applying them, and the inspection and testing procedure shall be included in the review of product requirements. In particular, the applicable requirements of ATP Annex 1, Appendix 1, shall be met.

Verification of the conformity of equipment which is not described above shall be submitted to the competent authority for examination.

Professional secrecy (i.e., design, manufacture, etc.) shall not apply to either administrative authorities or the competent authority, whose entire staff, including its auditors, is bound by professional secrecy for all matters directly or indirectly related to the equipment under regulation.

This subclause is not always required and is subject to exclusions according to the limitations set out in 1.2 above. However, should the manufacturer invoke the first two lines in the adaptation tables given in Annex 1, the general requirements of this chapter shall be applicable for the relevant changes in design.

For professionals who carry out the thermal re-insulation of insulated or mechanically refrigerated tanks, design validation shall be performed by carrying out a type test, in an official station, on thermally re-insulated equipment in which the thermal characteristics may vary considerably from those of the initial equipment due to the impact of thermal re-insulation processes.

Any change in design and development shall be

identified and records maintained.

A review of these changes shall include an assessment of how the changes affect the product component and the product already delivered. The manufacturer shall establish, in particular, that the product complies with a type of equipment which has been subjected to a test report issued by an official testing station, or corresponds to a type regarded as equivalent (e.g. requesting an addendum to a test report to include a new, more powerful type of compressor on a thermal appliance).

Any change with respect to the certified type defined in the test report (e.g., replacement of a two-leaved rear opening with a curtain, creation of an additional opening) shall be submitted to the competent authority. In this case, the change (excluding those covered by adaptations) made by the original body maker, or by another body maker qualified by the original body maker, shall always include an efficiency test in a testing centre, except if the new configuration corresponds to a type of equipment covered by a valid test report, or is made to take account of adaptations made on the equipment in question.

The manufacturer shall ensure that the purchased product or service complies at all times with the specified purchasing requirements.

As process outsourcing affects the compliance of equipment with the regulatory requirements, when it relates to product realization (subclause 7) or to measurement, analysis and improvement (subclause 8), it must be controlled. The manufacturer must be able to demonstrate its ability to continuously control the outsourced process(es) in respect of the relevant technology, even in the event of a failure of the suppliers.

Note: a “**supplier**” means any organization or person who provides a product or service (e.g., for manufacturers, a fitter of refrigeration units on a body; for assemblers, a manufacturer of insulating panels). A supplier can be either internal or external to the company. It may be referred to as a “contractor” or “subcontractor”.

7.4. Purchasing

7.4.1. Purchasing process

7.4.2. Purchasing information

7.4.3. Verification of purchased product

The declaration of conformity process, which includes the certificate application, may not be outsourced.

The company specifies how it handles its suppliers involved in the manufacturing, reconditioning or thermal re-insulating process when those suppliers are not directly certified according to this reference document. In addition, the company should set up a system to assess non-certified suppliers. This assessment system may either consist in a compliance check (with respect to the specified purchasing requirements) on receipt of the products used in construction, whenever possible, and/or possible visits to the production site, or by ensuring that the supplier is recognized by a competent authority.

The existence, on purchased equipment parts, of a compliance certificate drawn up by its supplier:

- Does not release the manufacturer from the responsibility to ensure the compliance of these such sub-assemblies or parts;
- Does not alter the manufacturer's responsibility.

For materials which provide, or help provide, insulation, the parameters used to maintain the thermal and physical properties of the insulating materials (e.g., density, thermal conductivity (λ), expansion gas, dimensions, etc.) are checked on a regular basis.

For purchases of other products, sub-assemblies or parts (e.g., units, panels, doors, seals, compressors, fluids, evaporators, condensers, engine-pulley kits, alternators, valves, etc.), purchasing information should, where applicable, include regulatory compliance with the official test report.

For refrigeration units (mechanical refrigeration, eutectic plates), the purchasing requirements (e.g., ordering the thermal dimensioning file) should aim at compliance with the unit reference test report and with the company's requirements relating to the output expected from the equipment under consideration.

This subclause, which is applicable to the component products of the manufactured

equipment, sub-assemblies or parts, also applies to subcontracted checking, testing, calibration and verification processes.

Outsourcing (subcontracting)

There can be several ways in which a critical process is outsourced (subcontracted) (this list is not exhaustive).

- **Outsourcing of the manufacture of the component sub-assemblies for equipment or body**

This relates to subcontracting the manufacture of critical body components (e.g., doors, insulating panels, panels, etc.). Sub-assemblies must comply with the description components of the official test report for the body in which the sub-assembly has been fitted. The company must demonstrate control of the subcontracting process by:

- Providing evidence that specifications listing the requirements applicable to the subcontracted sub-assembly have been provided to its supplier and that the order explicitly targets these requirements; and
- Providing evidence that the manufactured sub-assemblies are compliant, either by auditing its supplier, or by carrying out an incoming inspection to check compliance with the specifications laid down.

Authorization of the supplier by a competent authority for the subcontracted activity constitutes adequate evidence of control over said supplier.

- **Outsourcing the assembly of a body kit or the adaptation of a body finished in the workshop**

The company shall demonstrate control of the subcontracting process by:

- Providing evidence that its supplier has the required skills and fitting procedures, and/or the additional kit adaptations supplied by the company; and
- Providing evidence that the assemblies and/or additional kit adaptations are compliant, either by auditing its supplier, or by setting up continuous compliance monitoring for the procedures performed by

said supplier.

Authorization of the supplier by a competent authority, for the subcontracted activity, constitutes adequate evidence of control over said supplier.

- Outsourcing the manufacture and/or fitting and/or commissioning of thermal appliances (does not apply to small containers)

7.5 Production and service provision

7.5.1 Control of production and service provision

7.5.1.(f)

7.5.2. Validation of processes for production and service provision

7.5.3. Identification and traceability

7.5.4. Customer property

7.5.5. Preservation of product

The manufacturer must be able to demonstrate that the manufactured equipment complies with the prototypes designed and built for a type test according to this reference document and ensure that its production is sufficiently uniform to guarantee this.

The company shall include the steps of applying for an ATP certificate in its planning, taking into consideration the issuance process required by the competent authority timewise.

Classification of the equipment under the ATP specification must be determined and formalized when the customer places the order.

There must be written procedures which clearly define the checking and control activities performed during production and final inspection, if these might affect the compliance of the equipment, as well as the equipment used and the personnel involved.

The supply of the documents required to properly use and to maintain the compliance of the equipment (operating instructions, ATP compliance certificates, regulatory markings, etc.) should be included in the service.

Documented processes must make it possible to determine, after the fact, for any equipment or equipment part that may be selected by the competent authority during or at the end of the manufacture process:

- Identification (official test reports or definition documents demonstrating compliance with the type);
- Destination (subject to regulations, customer, etc.);
- Composition (including the origin of subcontracted components);
- Any checks undergone;

- Sanctions resulting from such checks.

In particular, the applicable requirements of ATP Annex 1, Appendix 1, paragraphs 4, 5 and 6, must be met.

Assemblers

Body assemblers must leave the original plate in place and file their certificate application with the manufacturer's body number. They may add a plate with their own reference number, but not substitute it for the original one. Traceability to the original body must be provided in any event.

Particular case

The equipment for which the certificate of technical compliance is being requested may be based on two certified types, thus using two testing reports which the manufacturer owns or has usage of, for adjoining compartments, each compartment meeting its certified type or allowed variations thereof (the thickness of the bulkhead which separates these two compartments shall be greater than or equal to the maximum thickness value of the relevant faces of the certified type defining each compartment).

When only one certificate is being requested for the equipment, the worst-case K coefficient is selected for the equipment.

When one certificate is being requested per compartment (having its own identification), then the K coefficient of each compartment is selected for certification of the compartment in question.

Equipment compliance study procedure leading to application for a certificate of technical compliance

The equipment for which the certificate of technical compliance is being applied may:

- Refer to a single prototype, in the usual conditions (see para. 7.); or
- Refer to two different prototypes, one for the body and the other for the thermal appliance. In the latter case, the applicant shall provide the following test reports:
 - that of the body, for measuring the overall heat transfer coefficient of the equipment

referred to for the K coefficient;

- that of the cooling appliance for:
 - measuring the overall heat transfer coefficient of the equipment fitted with the refrigerating equipment referred to;
 - determining the effectiveness of the refrigerating equipment to which it refers. This test report may only be used for the class specified in the conclusion.

Month and year of manufacture

The month and year of manufacture of the equipment specified in the certificate application must match the date of manufacture of the body (i.e. construction) or kit (in the latter case, this is the date of manufacture of the kit components, rather than the date of assembly), even if the equipment has not been in operation since that date.

If a used refrigeration unit is fitted onto a new body, a temperature holding test or a temperature decrease test is required when the unit has been in operation more than 100 h or more than 1 year (road or thermal) after its date of manufacture.

Handling/Preservation of the product

The specific conditions of storage must be defined in close relationship with the analysis of critical points for the final quality of the manufactured equipment. In addition, some storage procedures may be regarded as manufacturing or inspection procedures (e.g. to stabilize insulating materials, etc.): the methods of storage should then be controlled and there should be records thereof.

7.6 Control of monitoring and measuring equipment

All equipment used for monitoring and measuring purposes must be:

- Calibrated or checked at regular intervals against standards that are connected to international standards.
- Identified and followed up to determine proper calibration.
- Protected against damage and deterioration.

This applies in particular to length, pressure, temperature, weight and time measuring

equipment.

For critical measurement means used in production and in final inspection, unless specifically provided for in a document, all working standards must feature a calibration certificate issued by a laboratory accredited by an accreditation body, bearing the accreditation body's logotype; in addition, the desired capability of the measuring means must be formally defined.

(1) An "accredited laboratory" is a calibration laboratory which has been accredited by a laboratory which is accredited by an accreditation body signatory to the EA multilateral recognition agreement (European cooperation for Accreditation) in calibration. In any event, the scope of accreditation should include the calibration possibilities and the relevant uncertainties.

8. Measurement, analysis and improvement

8.1. General

8.2. Monitoring and measurement

8.2.1. Customer satisfaction

8.2.2. Internal audit

8.2.3. Monitoring and measurement of processes

8.2.4. Monitoring and measurement of product

8.3. Control of non-conforming product

8.4. Analysis of data

8.5. Improvement

8.5.1 Continual improvement

8.5.2 Corrective action

8.5.3 Preventive action

There shall be no waiver of the regulatory criteria applicable to manufactured equipment. The manufacturer shall maintain a record of the actions taken subsequent to the rejection of equipment or a batch of equipment during final inspection (modification, disposal, destruction, etc.).

The company shall use appropriate methods to monitor processes. These methods must lead to curative actions (or corrections) and corrective or preventive actions to ensure compliance of the product.

The company shall monitor and measure product characteristics (e.g. dimensions, markings, inside/outside equipment) to check that the product requirements are met.

Proof of compliance must be preserved, as well as proof that any noted or potential non-conformity has been dealt with.

The company shall ensure that the product or component of the product which does not conform to the product requirements is identified and controlled to prevent its unintentional use or supply, for instance, as a result of mishandling.

Inspections and any associated responsibilities and authorities in the handling of non-conforming products or product components

shall be defined in a documented procedure.

The company shall deal with the non-conforming product or product component in one of the following ways:

- By conducting actions to remove the detected non-conformity;
- By conducting actions to prevent it being used or applied as originally planned.

When a product or component of a product is corrected, it must be checked again to demonstrate that it meets the requirements.

Any agent applying for a certificate must set up a procedure to process any non-compliances affecting the certificates being applied for, including when the certificates have been sent to the customer. These procedures must take into account the information resulting from the assessments performed by the competent authority when the certificate is applied for and additional information is requested, or from possible rejections.

Table 1

Adaptations to obtain certificate of technical compliance for international carriage (ATP)

Adaptation allowed: green (or light grey if displayed in black and white)

Adaptation not allowed: red (or dark grey if displayed in black and white)

Openings as per reference equipment (test report)	Alterations not impeding issuance of ATP certificate												Equivalents
	Green	Green	Green	Red	Red	Green	Green	Red	Green	Green	Red	Green	
	Red	Green	Green	Red	Red	Green	Green	Red	Green	Green	Red	Green	
	Red	Green	Green	Red	Red	Green	Green	Red	Green	Green	Red	Green	
	Red	Green	Green	Red	Red	Green	Green	Red	Green	Green	Red	Green	
	Red	Green	Green	Red	Red	Green	Green	Red	Green	Green	Red	Green	
	Red	Green	Green	Red	Red	Green	Green	Red	Green	Green	Red	Green	
	Red	Green	Green	Red	Red	Green	Green	Red	Green	Green	Red	Green	
	Red	Green	Green	Red	Red	Green	Green	Red	Green	Green	Red	Green	
	Red	Green	Green	Red	Red	Green	Green	Red	Green	Green	Red	Green	
	Red	Green	Green	Red	Red	Green	Green	Red	Green	Green	Red	Green	
	Red	Green	Green	Red	Red	Green	Green	Red	Green	Green	Red	Green	
	Red	Green	Green	Red	Red	Green	Green	Red	Green	Green	Red	Green	
n multi-wing doors m single-wing doors	Red	Green	(n + m) maximum multi-wing										