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COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the
Transport of Dangerous Goods

Twenty-fifth session, 5-14 July 2004
Item 2 of the provisional agenda

TRANSPORT OF GASES

Alternatives to the waterbath test for aerosol dispensers

Transmitted by the European Aerosol Federation (FEA)

Executive summary

Every filled UN 1950 aerosol is subjected to a test performed in a hot water bath. This requirement is laid down in 6.2.4.
This document proposes to separate requirements for UN 1950 aerosols from requirements for small receptacles containing gas (UN 2037 gas cartridges) and to include requirements for an alternative to the water bath test for aerosol dispensers.

Related documents

ST/SG/AC.10/C.3/2003/51 - (FEA) Alternatives to the Waterbath Test for Aerosol Dispensers
UN/SCETDG/23/INF.49 - (FEA) Alternatives to the Waterbath Test for Aerosol Dispensers

Background

1. During the 24th session of the Sub-Committee in December 2003, FEA made a proposal in ST/SG/AC.10/C.3/2003/51 to allow alternative test systems to the current hot water bath. The proposal received a number of comments and some concerns were raised as well as support for alternatives in principle. FEA agreed to submit a revised proposal for the next session.

2. FEA recalls that the following concerns were raised:

   (a) Alternative systems should remain under the control of the competent authority;

   (b) Experience should be gained with one alternative, which had been tested by FEA;

   (c) Adequate guidelines for application of the proposed alternative should be included, avoiding inconsistent interpretation by different producers and/or countries.

3. FEA has considered the above points and has prepared a revised proposal based on the alternative trial as detailed in UN/SCETDG/24/INF.49.

4. FEA has discussed the proposal with AEROBAL.

Proposal

5. The water bath alternative approach tested by FEA is an integrated Quality Assurance and testing package involving the can and valve manufacturers and the aerosol filler. It is based on the principle that Quality Assurance and on-line testing may be used to ensure that all faulty aerosols are eliminated before they leave the filling line. The tested water bath alternative has the following key elements:

   (a) Quality assurance procedures are used by the can maker to ensure that only cans that are pressure stable and leak-tight are supplied to the filler. Central to this is for all cans to be leak and pressure tested to a pressure equal to or in excess of the maximum expected in the filled aerosols at 55 °C (50 °C if the liquid phase does not exceed 95% of the capacity of the receptacle at 50 °C);

   (b) Quality assurance procedures are used by the valve supplier to ensure that only valves that have all their components in place and will be pressure stable and leak tight once crimped on a can are supplied to the Filler;

   (c) Quality assurance systems are used by the Filler during handling and filling to ensure that all aerosols are neither over filled nor over-pressurised and that the valve crimp is pressure stable and leak tight, enabling only high quality aerosols to be produced. This includes:

      - Checks on setting and maintaining the correct valve crimp dimensions.
      - In-line check-weigher system to ensure overfilled aerosols are rejected.
      - A micro-leak detector on the filling line to test the valve and valve crimp integrity of all filled aerosols for leaks.

6. Based on this FEA proposes a new form of words for the clause 6.2.4 Requirements for aerosol dispensers and small receptacles containing gas (gas cartridges):

"6.2.4 Requirements for aerosol dispensers and small receptacles containing gas (gas cartridges)

6.2.4.1 Small receptacles containing gas (gas cartridges)

6.2.4.1.1 Each receptacle shall be subjected to a test performed in a hot water bath; the temperature of the bath and the duration of the test shall be such that the internal pressure reaches that which would be reached at 55 °C (50 °C if the liquid phase does not exceed 95% of the capacity of the receptacle at 50 °C). If the contents are sensitive to heat or if the receptacles are made of plastic material which softens at this temperature, the temperature of the bath shall be set at between 20 °C and 30 °C but, in addition, one receptacle in 2000 shall be tested at the higher temperature.

6.2.4.1.2 No leakage or permanent deformation of the receptacle may occur, except that a plastic receptacle may be deformed through softening provided that it does not leak.

6.2.4.2 Aerosol dispensers

Each filled aerosol shall be subjected to a test performed in a hot water bath or a validated water bath alternative.

6.2.4.2.1 Hot waterbath test

6.2.4.2.1.1 The temperature of the water bath and the duration of the test shall be such that the internal pressure reaches that which would be reached at 55 °C (50 °C if the liquid phase does not exceed 95% of the capacity of the aerosol dispenser at 50 °C). If the contents are sensitive to heat or if the aerosol dispensers are made of plastics material which softens at this test temperature, the temperature of the bath shall be set at between 20 °C and 30 °C but, in addition, one aerosol dispenser in 2000 shall be tested at higher temperature.

6.2.4.2.1.2 No leakage or permanent deformation of an aerosol dispenser may occur, except that a plastic aerosol dispenser may be deformed through softening provided that it does not leak.

6.2.4.2.2 Alternative tests

With the approval of the Competent Authority, the following procedure may be followed:

6.2.4.2.2.1 Quality Assurance Systems

6.2.4.2.2.1.1 General requirements for all

The can and valve manufacturers and aerosol filler must have Quality Assurance systems based upon ISO9001 including the following parameters:

(a) [The company has a quality manual in place and carries out internal audits to verify adherence to its systems;]

(b) Components are identifiable so that they can be traced back to the manufacturer's batch number and production records retrieved;

(c) [All quality documents must be issued under the authority of the Quality Assurance manager. There must be stringent document control which assures that procedures are in accordance with the correct document revision: unauthorised changes to procedures do not occur and all production quality documentation is collated and retained for at least five years;]

(d) The filler must receive the supplier certification for the components before they are released to production. [The filler must carry out periodic inspections of suppliers for compliance with agreed quality procedures;]

(e) All test equipment that is critical to quality is identified with a unique number and routinely calibrated;

(f) If too many units are ejected from the filling line as non-conforming, then production is stopped and the batch quarantined. The management will inspect the quarantined stock and decide if it is satisfactory and what corrective action is required;

(g) Minor corrective actions carried out by the production team under appropriate supervision, are recorded. Production management review minor corrective actions. Major corrective actions are authorised and recorded by the production management;

(h) [Legible quality records must be in place;]

(i) [During assembly, in-process inspection and testing is in place to ensure adherence to the product specifications;]

(j) [The final product undergoes a final inspection and testing protocol;]

(k) Procedures ensure that there is no damage to final product.

6.2.4.2.2.1.2 Specific to the can maker

The can maker shall pressure test each completed can to a pressure equal to or in excess of the maximum expected in the filled aerosols at 55 °C (50 °C if the liquid phase does not exceed 95% of the capacity of the receptacle at 50 °C). This shall be at least two-thirds of the deformation rating of the can. If a leak occurs, the can will be rejected. The can shall only be supported at the neck. A functionality test shall be carried out on the unit prior to each test to ensure it will detect a pressure increase and the performance continuously monitored to ensure it is not acting erroneously.
The requirement of the performance of the can pressure test unit is to detect a leak rate of equal to or greater than 3.3×10^{-2} mbar.l.s^{-1} at the test pressure.

6.2.4.2.2.1.3 Specific to the valve maker

Procedures ensure that only valves that have all their components in place and will be pressure stable and leak tight once crimped on a can are supplied to the Filler.

6.2.4.2.2.1.4 Specific to the aerosol filler

The aerosol filling line shall be of a standard configuration with the following key elements:

(a) Valve crimper:
At the start of a product changeover that requires the crimping head to be reset, the integrity of the new crimp setting shall be proven by placing the aerosol in a laboratory water bath;

(b) Correct propellant:
Ensure correct propellant and fill weights are used;

(c) In-line check weigher:
Each filled aerosol shall be weighed to check that it is not over filled, for a liquefied gas this will also eliminate any aerosols that are over-pressurised. A system shall be in place to automatically reject any over filled aerosols from the filling line into a waste container;

(d) Valve and crimp leak detector:
Each filled aerosol shall be placed in a head that covers the whole valve and will detect a leak from the valve crimp or the valve itself. The required performance is to detect a leak rate of equal to or greater than 2.0×10^{-3} mbar.l.s^{-1} at 20°C. A system shall be in place to automatically reject any leaking aerosols from the filling line into a waste container.

6.2.4.2.2.2 Verification of the Alternative Approach

An inspection body (see 6.2.1.8) shall validate the alternative test procedure using audits based upon ISO9001 carried out at the can and valve manufacturers and aerosol filler to ensure that Quality Assurance systems are in place and functioning correctly. Any critical issues for the System must be resolved and the system re-audited before continuing with this Alternative Approach.

[6.2.4.2.2.3 The Competent Authority shall require the holder of the approval, upon request, to provide the evidence demonstrating compliance with this alternative approach to any other competent authority who requests such evidence.]

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