

**Annex 1: Draft
Improvement Notice.** To:

Name

Address

Trading as

Inspector's full name I,

Inspector's official Designation One of Her Majesty's Inspectors of Health and Safety, being an Inspector appointed by an instrument in writing made pursuant to Section 19 of the said Act and entitled to issue this Notice

Official address of

Telephone Number

Hereby give you notice that I am of the opinion that

Location of premises or place of activity at

You, as a manufacturer (or consignor or packer as the case may be) of aerosol dispensers

Are contravening

have contravened in circumstances that make it likely that the contravention will continue or be repeated

the following statutory provisions:

Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 Regulation 5

The reason for my said opinion are:

That you are not carrying out leak testing of aerosol dispensers as required by paragraph 6.2.6.3 of ADR

Date for compliance **And I hereby require you to remedy the said contraventions or, as the case may be, the matters occasioning them, by** [Insert expiry date]

And I direct that the measures specified in the Schedule which forms part of this Notice shall be taken to remedy the said contraventions or matters

Signature

Date

Schedule

To comply with this notice you should install and operate a leak test regime that either complies with the relevant parts of ADR at paragraph 6.2.6.3 which are reproduced below or which complies with paragraph 6.1.4 of the Annex to Council Directive 75/324/EEC (the “Aerosol Dispensers Directive”)

You should be able to show that the leak test scheme has been validated and is subject to an auditable quality control process.

Note that any alternative to water bath testing must be approved by the competent authority (Department for Transport). ADR 6.2.6.3.3.2.2 refers.

Useful information on leak testing may be found in the relevant parts of the latest edition of the “BAMA Standard for Consumer Safety and Good Manufacturing Practice” published by the British Aerosol Manufacturers’ Association, Kings Buildings, Smith Square, London SW1P 3JJ www.bama.co.uk

Extract from ADR

6.2.6.3.2 Aerosol dispensers

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

6.2.6.3.2.1 Hot water bath test

6.2.6.3.2.1.1 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 the higher temperature.

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

6.2.6.3.2.2 Alternative methods

With the approval of the competent authority alternative methods which provide an equivalent level of safety may be used provided that the requirements of 6.2.6.3.2.2.1, 6.2.6.3.2.2.2 and 6.2.6.3.2.2.3 are met.

6.2.6.3.2.2.1 Quality system

Aerosol dispenser fillers and component manufacturers shall have a quality system. The quality system shall implement procedures to ensure that all aerosol dispensers that leak or that are deformed are rejected and not offered for carriage.

The quality system shall include:

- (a) a description of the organizational structure and responsibilities;
- (b) the relevant inspection and test, quality control, quality assurance, and process operation instructions that will be used;
- (c) quality records, such as inspection reports, test data, calibration data and certificates;
- (d) management reviews to ensure the effective operation of the quality system;
- (e) a process for control of documents and their revision;
- (f) a means for control of non-conforming aerosol dispensers;
- (g) training programmes and qualification procedures for relevant personnel; and
- (h) procedures to ensure that there is no damage to the final product.

An initial audit and periodic audits shall be conducted to the satisfaction of the competent authority. These audits shall ensure the approved system is and remains adequate and efficient. Any proposed changes to the approved system shall be notified to the competent authority in advance.

6.2.6.3.2.2.2 Pressure and leak testing of aerosol dispensers before filling

Every empty aerosol dispenser shall be subjected to a pressure equal to or in excess of the maximum expected in the filled aerosol dispensers 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 design pressure of the aerosol dispenser. If any aerosol dispenser shows evidence of leakage at a rate equal to or greater than 3.3×10^{-2} mbar.l.s⁻¹ at the test pressure, distortion or other defect, it shall be rejected.

6.2.6.3.2.2.3 Testing of the aerosol dispensers after filling

Prior to filling the filler shall ensure that the crimping equipment is set appropriately and the specified propellant is used.

Each filled aerosol dispenser shall be weighed and leak tested. The leak detection equipment shall be sufficiently sensitive to detect at least a leak rate of 2.0×10^{-3} mbar.l.s⁻¹ at 20 °C.

Any filled aerosol dispenser which shows evidence of leakage, deformation or excessive weight shall be rejected.

6.2.6.3.3 With the approval of the competent authority, aerosols and receptacles, small, containing pharmaceutical products and non flammable gases which are required to be sterile, but may be adversely affected by water bath testing, are not subject to 6.2.6.3.1 and 6.2.6.3.2 if:

They are manufactured under the authority of a national health administration and, if required by the competent authority, follow the principles of Good Manufacturing Practice (GMP) established by the World Health Organization (WHO) 4; and

An equivalent level of safety is achieved by the manufacturer's use of alternative methods for leak detection and pressure resistance, such as helium detection and water bathing a statistical sample of at least 1 in 2000 from each production batch

6.2.6.4 Reference to standards

The requirements of this section are deemed to be met if the following standards are complied with:

- for aerosol dispensers (UN No. 1950 aerosols): Annex to Council Directive 75/324/EEC as amended by Commission Directive 94/1/EC1;
- for UN No. 2037, small recipients containing gas (gas cartridges) containing UN No. 1965, hydrocarbon gas mixture n.o.s, liquefied: EN 417:2003 Non-refillable metallic gas cartridges for liquefied petroleum gases, with or without a valve, for use with portable appliances - Construction, inspection, testing and marking.