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-fourth session
Geneva, 3-10 December 2003
Item 2 of the provisional agenda

TRANSPORT OF GASES

Alternatives to the Waterbath Test for Aerosol Dispensers

Transmitted by the European Aerosol Federation (FEA)

Related documents

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

Background

Following the results of a trial held at Wella's aerosol factory in Germany between July 2002 and June 2003, FEA proposes requirements for alternatives to the water bath test for aerosol dispensers (see working document ST/SG/AC.10/C.3/2003/51).

An independent inspection body, Burgoyne Consultants Ltd (BCL) (www.burgoynes.co.uk), verified that the extensive comparative trial adhered to the developed protocol for validation and produced true and accurate results.
Based on the inspection body's trial report, the FEA concluded that the developed protocol for validation is a suitable method to validate a water bath alternative system.

This informal document provides the FEA trial report.

REPORT OF A COMPARATIVE TRIAL
OF A WATER BATH TEST WITH AN
'ALTERNATIVE SYSTEM'

WELLA, HUNFELD, GERMANY,
JULY 2002 – JUNE 2003

FEA October 2003

EXECUTIVE SUMMARY

Aerosols have been in commercial production for over fifty years. Today, thousands of millions of aerosols are used annually and some modern aerosol filling lines can operate at high speed, producing up to 350 aerosols per minute. Aerosols use pressure from a liquefied or compressed gas (propellant) to provide the driving force to dispense the product from the can. The internal pressure from the propellant means that aerosols store a significant amount of energy which if suddenly released would have the potential to rupture (i.e. burst) the can. The result could be a rocketing aerosol or the release of a flammable gas which may pose a fire or explosion hazard.

To protect the consumer from the inherent hazards associated with aerosols, it is necessary to ensure that the manufacturing process produces aerosols that will not leak or burst. To this end, the regulations covering the manufacture and transport require that each filled aerosol is immersed in a bath of hot water for sufficient time (at least two to three minutes) to raise the internal pressure to that experienced at an equilibrium temperature of 55ºC (50ºC if the liquid phase at 50ºC does not exceed 95% of the capacity). The purpose of the hot water bath test is to ensure that all aerosols are pressure stable and leak tight. There are a few exceptions to this requirement that are based on can size and the nature of the product, but it can be claimed that every aerosol that passes through the water bath, in which every single aerosol is monitored corresponding to best practice, can be considered as pressure and leak tested.

Historically the water bath has proven to be a very effective test as is demonstrated by the very small number of incidents involving aerosols. However, it should be recognised that, particularly for today's high-speed aerosol production lines, there can be real problems at existing factories with larger water baths, not because of their effectiveness in pressure testing aerosols, but in achieving the environmental and manufacturing efficiencies required today.

The EC Directive allows that *"any test system enabling a result equivalent to that of the water bath method to be obtained may be used"*, but requires prior approval of the system by a special committee. The UN Regulations do not currently have a mechanism for alternative test systems to be approved.

The European Aerosol Federation (FEA) has investigated a number of different possible methods equivalent to the hot water bath test. It concluded that for an 'alternative system' to be comparable, then it must be capable of ensuring two conditions:

- that the filled aerosol will not weaken or fail if the internal pressure reaches the pressure of the contents at 50°C (maximum two-thirds of the 'test pressure' of the empty can following the EC Aerosol Directive 75/324/EEC[1]);
- that the aerosol will not leak at a rate where it poses a risk of a flammable atmosphere developing during transport, storage or in possession of the consumer.

FEA also concluded that the best way to demonstrate that an 'alternative system' is as effective as the hot water bath test is to conduct an extensive comparative trial.

[1] Following the EC Aerosol Directive 75/324/EEC, the 'test pressure' means the pressure to which an unfilled aerosol dispenser container may be subjected for 25 seconds without any leakage being caused or, in the case of metal or plastic containers, any visible or permanent distortion except a slight symmetrical distortion of the base or one affecting the profile of the upper casing shall be allowed provided that the container passes the bursting test.

FEA has developed a protocol for validation which states that:

> *Any 'water bath alternative' system must be validated by running it prior to and in series with a fully functioning water bath for a significant number of aerosols, to be defined and agreed prior to commencing the trial. During the trial no aerosols shall burst on the line or in the water bath under normal running conditions and the 'alternative system' shall be as effective as the water bath in identifying aerosols that leak. The trial shall be verified by a suitably qualified independent inspection body.*

To demonstrate that the protocol works, FEA established a validation trial for an 'alternative system' proposed by Wella AG based upon an integrated approach between the can manufacturers, valve manufacturers and the aerosol fillers. Strict quality assurance procedures are used to enforce stringent controls on the valve and aerosol can manufacture to ensure that the filler receives only high quality can and valve components. In addition to the quality assurance, every empty can is pressure and leak tested to a pressure equal to or in excess of that expected in the filled aerosol at 50°C before leaving the can manufacturer. A similar system at the filler provides controls to ensure that the aerosols are filled with the correct product and propellant, are check weighed to ensure the correct fill and, finally, every filled aerosol is leak tested around the valve area.

FEA appointed Burgoyne Consultants Ltd (BCL) (www.burgoynes.co.uk) as a third party independent auditor to verify the trial.

The trial was held at Wella's aerosol factory at Hunfeld, Germany between July 2002 and June 2003. The trial used only three-piece tinplate aerosols as it was not possible to obtain supplies of aluminium cans which had been pressure and leak tested to the requirements of 'alternative system'.

The results of the trial can be summarised as

- Over 12 million aerosols were subjected to the protocol.
- No aerosols tested by the 'alternative method' subsequently burst in the hot water bath test.
- 96 aerosols were identified as leaking by both test systems.
- 107 aerosols were identified as leaking by the hot water bath test.
- 104 aerosols were identified as leaking by the 'alternative system'.

It is the opinion of Burgoyne Consultants Limited that the trial succeeded in validating the specific 'alternative system' proposed by Wella and validates the FEA protocol for assessing any future, different alternative test systems. The 'alternative system' trialled ensured that the aerosols were pressure stable and was comparable to the water bath in detecting leaking aerosols.

CONTENTS

1. INTRODUCTION

Aerosols have been in commercial production for over fifty years. Over this period the design, manufacture, and filling has undergone substantial development and with ever increasing consumer demands for more aerosols will continue to do so. In 2002 about 4.3 billion aerosols were manufactured in the EU, 3.5 billion in the USA and it is believed that total global production is around 10 billion. Consequently modern filling lines tend to operate at high speeds with some filling up to 350 aerosols per minute, although many still run at lower speeds.

Aerosols use pressure from a liquefied, or compressed gas (propellant) to provide the driving force to dispense the product from the can. The internal pressure from the propellant means that aerosols store a significant amount of energy which has the potential to rupture (i.e. burst) the can and could give rise to projectiles. In addition, most of the liquid gas propellants used are extremely flammable (e.g. propane/butane mixes, or dimethyl ether (DME)) and many other ingredients are flammable and if suddenly released may pose a fire or explosion hazard. If the can did not burst but developed a fault that allowed product and propellant to leak, then if ignited immediately, a jet flame would form. If the leak is not ignited, in a poorly ventilated space a flammable atmosphere may also form, which if ignited may cause a flash fire or, if the space, is small and confined, an explosion. It is, therefore, very important that the integrity of the pack is assured during the manufacturing process.

To prevent uncontrolled releases from aerosols, the aerosol industry recognised the need to verify the integrity of each aerosol. Trials carried out in 1946 in the Mojave Desert, USA, demonstrated that in hot climates aerosols experience temperatures of around 50ºC. At this temperature the internal pressure in an aerosol containing LPG propellant will increase to around 8 barg. As a result the water bath test method was developed. This involves immersing the aerosols in hot water for a time (at least two to three minutes) sufficient to raise the internal pressure to that experienced at an equilibrium temperature of 55ºC (50ºC if the liquid phase at 50ºC does not exceed 95% of the capacity). The test allows visual determination of pressure stability and leak tightness by checking that the aerosols do not burst, do not leak (evident by gas bubbles in the water) and do not deform.

The UN Model Regulations, the EC Directive on Aerosols (75/324/EC) and national regulations in other countries take advantage of this work and require all aerosols to undergo immersion in the hot water bath test to prove that each aerosol is pressure stable and leak free. The EC Directive also permits alternative test systems providing that they are proven to be as effective as the water bath test.

However, when the water bath was developed typical line speeds were about 40-60 aerosols per minute, much slower than the 350 aerosols per minute achieved by some modern manufacturing equipment. The consequence is that today a modern water bath may be up to 10 times larger than one needed when the test method was developed over fifty years ago. With the continual drive to improve environmental and manufacturing efficiencies and the use of faster filling lines larger baths can present real problems, not because of their effectiveness in pressure testing aerosols, but with space requirements, cost of running and disposal of contaminated water from the bath.

Therefore for several years the European Aerosol Federation (FEA) has been investigating possible alternatives to the traditional hot water bath test with the aim of identifying an approvals protocol. FEA concluded that the best way to demonstrate that any 'alternative system' is as effective as the water bath is to conduct an extensive comparative trial.

FEA has developed a protocol for validation that states:

> *Any 'water bath alternative' system must be validated by running it prior to and in series with a fully functioning water bath for a significant number of aerosols, to be defined and agreed prior to commencing the trial. During the trial no aerosols shall burst on the line or in the water bath under normal running conditions and the 'alternative system' shall be as effective as the water bath in identifying aerosols that leak. The trial shall be verified by a suitably qualified independent inspection body.*

To demonstrate that this protocol works, FEA selected an 'alternative system' which was proposed by Wella AG based on the following integrated system:

- High level quality assurance procedures in place for the valve and can manufacture to ensure only high quality components are used by the filler.
- A pressure test for all empty aerosol cans by the can manufacturer to a pressure equal to or in excess of the maximum expected in the filled aerosols at 50°C.
- High level quality assurance in place during aerosol handling and filling to ensure that only high quality aerosols are produced that include:
    - a) checks on setting and maintaining the correct valve crimp dimensions.
    - b) 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 of all filled aerosols for leaks.

A fuller description of the 'alternative system' is presented in Section 5.

This report describes the validation trial held at the Wella aerosol factory in Hunfeld, Germany from July 2002 to June 2003.

2. POTENTIAL HAZARDS FROM AEROSOLS

As described above the main hazards arise from the aerosol bursting or leaking flammable propellant and/or product. If an aerosol bursts the stored energy will be suddenly released and may cause the aerosol to be projected or the valve cup to fly off. If the propellant and/or product base is flammable, a bursting aerosol will result in a sudden release of flammable gas. If the bursting aerosol is in a large, open building, ignition of the released flammable material may create a flash fire or fireball with minimal overpressure. This could, however, escalate to involve other aerosols or combustible material resulting in a serious fire. If, however, an aerosol was to burst in a confined volume (e.g. in a kitchen cupboard) the released flammable material could result in an explosion, which may cause destruction of the enclosure. On the other hand, leaking aerosols will not result in a sudden release of flammable material and in a room with good ventilation will result in the extent of flammable volume created being minimal. If the release is into a small poorly ventilated enclosure it may be possible to generate a flammable atmosphere occupying a large proportion of the enclosure, representing an explosion hazard.

There is a wide variety of potential theoretical causes for aerosols leaking or bursting some of which are listed below:

- Pinhole leaks as a result of inclusions in the metal used to fabricate the can.
- Leaking from top and bottom seams.
- Leaking from the weld, especially at the ‘triple points’ where the weld meets the top and bottom seams.
- Leaking from beneath the valve cup.
- Missing valve components.
- Incorrect setting, or faulty operation of a crimp head
- Aerosols may become trapped in and damaged by star wheels, scrolls, pick and place units, pusher bars etc. during the filling process.
- If the stem is misaligned with the nozzle, then the stem may be damaged during gassing or buttoning resulting in a leaking aerosol.
- Poorly adjusted, or malfunctioning, product and/or gasser heads may result in aerosols being overfilled with product or propellant.
- An aerosol could be charged with the wrong propellant, or else a supplier may inadvertently supply LPG with too high a vapour pressure for the can filled.

It should be noted that these faults generally occur at very low levels with modern manufacturing methods.

3. THE WATER BATH TEST

The purpose of the water bath test is to manage the risks inherent with the manufacture, storage and use of aerosols. Modern filling lines often have built in systems such as check-weighers and gas detectors to identify a leaking aerosol even before it reaches the water bath and any alternative test system will need similar checks. Aerosols being damaged during storage and distribution or as a result of can corrosion clearly arise after Water Bath testing so that the use of the Water Bath does not influence their risk.

Water Bath testing has been undertaken successfully for many years and has been found to perform two functions:

a) Increasing the internal pressure to confirm that the aerosol will not burst or deform if subjected to high ambient temperatures.

b) Providing a means for detecting leakage from a filled aerosol.

To detect leaking aerosols in the bath, they were originally under continuous visual surveillance, with operators looking for bubbles emerging from cans. When such bubbles were observed the operator would stop the line and remove the leaking aerosol. This approach continues to be used today by some fillers, but with the faster line speeds devices have become available to automatically detect leaking aerosols in a Water Bath. Devices that are available use measuring techniques based on differential pressure, conductivity or gas concentration. In practice, it is extremely unlikely that any leaking aerosols will present a hazard to a consumer. An aerosol with a large leak will have discharged itself before leaving the filling line. Any leaking aerosol on the filling line that is still leaking when it is purchased must be leaking at such a small rate as not to present a hazard. Thus the water bath test identifies intermediate leaks. It is accepted in the aerosol industry that aerosols micro-leak at a rate of one to three grammes per year. There are no reported incidents to suggest that such a small leak rate constitutes any fire or explosion risk in transport, distribution or consumer use.

Fillers occasionally witness aerosols bursting in Water Baths and they also report experiencing occasional events of reversal of the aerosol bottom or deformation of the top, which can be viewed as precursors to aerosol failure. Such failures and deformations of aerosols occur very infrequently (e.g. in 1997 the Dutch Aerosol Association, NAV, reported 50 bursts of tin and aluminium aerosols in the Water Bath for 150 million aerosols produced).

Despite the potential hazards associated with aerosol containing flammable propellants, the safety record in relation to aerosols in use would appear to be extremely good. There have been very few reported incidents of significant consequences. However, data in relation to incidents would appear to be very scarce. Historical evidence indicates that in most of the reported cases where problems of aerosols apparently not being pressure stable have arisen, the cause has been attributed to damage to the aerosol post manufacture (i.e. abuse).

From the above it can be concluded that Water Baths, when correctly used, provide a good means of identifying aerosols which may be prone to bursting (i.e. those which are not pressure stable). However, on modern high speed lines they may not represent an effective means of detecting leaking aerosols unless reliable automatic leak detectors are also installed to replace the manual visual detection of leaks.

4. REQUIREMENTS FOR AN ALTERNATIVE TEST SYSTEM

It is FEA's view that any 'alternative test system' has to be equivalent to the current water bath test. To this end the 'alternative system' must satisfy the following conditions:

a) Any 'alternative test system' must be safe to operate and adhere to the safety legislation in the country where it is to be operated. It may only be used with the agreement of the appropriate Competent Authority.

b) Any 'alternative test system' must be validated by comparison with the traditional water bath. It must not allow any aerosols to pass that subsequently burst or deform in a water bath that is operating under its normal conditions.

c) Any 'alternative system' must be shown to be as effective at identifying leaking aerosols as the water bath.

d) An independent assessor must verify the 'alternative system'.

In order to satisfy these conditions any 'alternative system' not heating the filled aerosols must include the following elements:

i) All empty cans must be pressure tested to at least two thirds of the test pressure defined in EC Aerosol Directive 75/324/EEC. In addition, on a statistical basis, a set number of cans must be pressure tested to full deformation and burst pressure. The requisite European test pressures are given in the table below.

Test pressure[2] (barg)	**Maximum internal pressure of the contents at 50°C (barg)**	**Required minimum pressure to test all empty cans (barg)**
18	12	12
15	10	10
14	9.3	9.3
12	8	8
10	6.7	6.7

ii) All empty cans must be tested to show a leak rate of less than 3.3×10^{-2}mbar.l.s^{-1} of air at 10 barg. It has been demonstrated that cans with a leak rate below this can be considered leak-tight as they will not present a hazard during storage, distribution or consumer use.

iii) Any 'alternative system' must include an accurate and reliable method of checking the fill.

Once verified, the alternative system must be documented and approved by the relevant national or international competent authorities. Following approval an identical system to the approved system may be commissioned and used elsewhere following an independent audit that demonstrates compliance with the approved system.

[2] Following the EC Aerosol Directive 75/324/EEC, the 'test pressure' means the pressure to which an unfilled aerosol dispenser container may be subjected for 25 seconds without any leakage being caused or, in the case of metal or plastic containers, any visible or permanent distortion except a slight symmetrical distortion of the base or one affecting the profile of the upper casing shall be allowed provided that the container passes the bursting test.

5. THE TRIAL

To demonstrate that the protocol works, FEA established a validation trial for an 'alternative system' proposed by Wella AG based upon an integrated approach between the can manufacturers, valve manufacturers and the aerosol fillers. Strict quality assurance procedures were used to enforce stringent controls on the valve and aerosol can manufacture to ensure that the filler received only high quality can and valve components. A similar system at the aerosol filler provided controls to ensure that the aerosols were filled with the correct product and propellant and were checked weighed to ensure the correct fill. In addition to the quality assurance, every empty can was pressure and leak tested before leaving the can manufacturer and every filled aerosol was also leak tested around the valve area. The Trial took place in Germany from July 2002 to June 2003 involving one valve manufacturer, two can manufacturers and the aerosol filler Wella. Equipment was used for the detection of any leaks from the empty cans and the filled aerosols. The water bath was equipped with a leak detector. A full description of the systems in place is given in Appendix 1, but in simple terms, the alternative system trialled by FEA is based on;

a) The can makers pressure testing every can for pressure stability and microleaks.
b) The valve maker ensuring that all valves supplied had all components in place and would be pressure stable and leak tight once crimped on a can.
c) The aerosol filler ensuring that aerosols were filled with the correct propellant and were not over-pressurised.
d) The aerosol filler ensuring that all filled aerosols were check weighed and rejected if they were under or overweight (overfilled).
e) The aerosol filler ensuring that the valve crimp was pressure stable and leak tight by a statistical check on can crimp dimensions.
f) The aerosol filler testing the valve and valve crimp integrity for microleaks once the aerosol had been filled. Because the empty can had been shown to be pressure stable and leak tight by the can manufacturer, only the valve and valve crimp needed to be leak checked after filling.
g) Strict compliance with written procedures in the manufacture of valves, cans and the filling of aerosols. This was to ensure that the controlled process that manufactured the aerosols does not solely rely on quality control checks to identify a faulty aerosol once it has been filled.

For a successful trial it was necessary to compare the performance of a water bath operated to the highest standards against the ‘alternative system’. The Water Bath used for the Trial was checked for compliance with the Regulations and had an automatic microleak detection system fitted (i.e. visual detection was not being relied on). During the trial the following leak rates were measured:

i) Can leak detector at the can manufacturer 3.3 x 10^{-2} mbar.l.s^{-1} at 20°C.

ii) Valve and crimp leak detector at the aerosol manufacturer 1 x 10^{-3} mbar.l.s^{-1} at 20°C.

iii) Hot water bath at the aerosol manufacturer 1 x 10^{-2} mbar.l.s^{-1} at 50°C.

FEA invited Burgoyne Consultants Limited (BCL) to act as independent auditors for the trial and consequently BCL carried out several audits during the trial (see Appendix 2). BCL also monitored, on a routine basis, the trial documentation and results and issued a monthly report to FEA on the performance of the trial. Particular attention was paid to check that the following conditions were met:

- Failure of any critical input or output control or measuring device in the 'alternative system' test method equipment did not result in any faulty or leaking cans to pass undetected. The fault was immediately revealed and the system stopped. The system was not allowed to be restarted until the fault is rectified and confirmed good.
- The QA procedures to ensure that should any critical device drift out of specification between maintenance periods then as a consequence the alternative system became more sensitive.
- Routine measurements ensured that crimping dimensions were set correctly and checked during operation.

The routine monitoring ensured that manual and automated computer trial production records were generated and cross-checked throughout the Trial. A data logging system recorded the information generated by the Trial. For each production day, the data were compiled into a daily spreadsheet that detailed how many cans were filled and how many were failed by the water bath, the alternative system or both systems. All aerosols rejected from the line were tested manually in a laboratory water bath to confirm if the rejected aerosol was truly leaking and to locate the source of the leak. The rejected aerosols passing the manual water bath test were termed 'false leakers' and returned to the filling line prior to the micro-leak detector at an appropriate time during the production run. Those aerosols that were found to be 'true leakers' were retained for further inspection. Each manual water bath test was recorded on an Evaluation Sheet. The manual records were reconciled with the computer data logger to ensure all rejected aerosols were being identified and recorded.

For validation purposes the Trial included over twelve million aerosols and utilized different can suppliers and can sizes. During the validation period, to test the robustness of the proposal many batches of aerosols were processed. The Trial considered tinplate steel single compartment aerosols only, as a supply of suitable aluminium cans was not available.

6. TRIAL RESULTS

6.1 Summary of Received Consolidated Sheets For Aerosol Manufacturer

The trial lasted twelve months between July 2002 and June 2003. During this period over 12 million aerosols were manufactured and every aerosol rejected by the water bath or the alternative system was logged. The table below summarises the monthly aggregated results, more details are given in Appendix 3.

Month	Total Production	**Rejected (corrected value)**			
		Figures from consolidation sheets	Figures from evaluation sheet		
		Total number of Leakers	Leak Detected by WB only	Leak Detected by LD only	Leak Detected by WB & LD
JULY 02	1 295 553	5			5
AUG 02	1 148 585	8	2	1	5
SEPT 02	432 495	17	1	1	15
OCT 02	843 810	7	1		6
NOV 02	1 847 295	4			4
DEC 02	878 580	0			
JAN 03	1 081 220	7	1		6
FEB 03	1 193 955	7			7
MAR 03	667 124	7	2		5
APR 03	188 145	1			1
MAY 03	1 173 225	34			34
JUNE 03	1 339 161	18	4	6	8
TOTAL	**12 089 148**	**115**	**11**	**8**	**96**

Total Production - this column shows the total number of aerosols filled during the month.

Rejected (corrected value) – this heading refers to aerosols rejected from the line and which have been subsequently tested to demonstrate they are true leakers.

Total number of leakers (Figures from consolidation sheets) – this column provides the number of true leakers as recorded by the computer generated daily consolidation sheets

Figures from evaluation sheet – these columns provides the number of true leakers as recorded by the manual laboratory water bath testing of all rejected aerosols.

The following nomenclature is used to identify which system has rejected the aerosol.

WB- detected by water bath

LD - detected by Leak Detector unit (i.e. the unit added to the line for the trial).

6.2 Statistics

Total number of aerosols filled	**12 089 148**
Corrected values	
Total number of aerosols rejected	**115**
Number of aerosols rejected by water bath	**107**
Number of aerosols rejected by leak detector	**104**
Uncorrected values	
Total number of aerosols rejected	**23 365**
Number of aerosols rejected by water bath	**2137**
Number of aerosols rejected by leak detector	**20 698**
Number of aerosol rejected by both systems	**530**

'Corrected value' refers to aerosols rejected from the line and have been subsequently tested to demonstrate they are true leakers.

'Uncorrected value' refers to all aerosols rejected from the line (i.e. including those which subsequent tests showed not to be leaking and returned to filling line).

The 107 aerosols rejected by the water bath is 0.00089% of the 12,089,148 filled aerosols. The 104 aerosols rejected by the alternative system is 0.00086% of the 12,089,148 filled aerosols. This does not represent a significant difference between the two systems.

7. DISCUSSION

7.1 Any proposed alternative test system must be able to demonstrate that it is as good as the water bath test at identifying leaking or pressure unstable aerosols. Any proposed 'alternative system' must therefore be validated by comparing its effectiveness with a water bath operated to the highest standards and which has gas detection fitted which identifies and automatically rejects leaking aerosols. The QA procedures at Wella assured that the water bath used in the trial was always above 50°C, the bath full of water, the aerosols being fully immersed and the residence time sufficient to raise the aerosol temperature to 50°C.

7.2 The Trial proved the protocol to demonstrate that an 'alternative system' is equivalent to the hot water bath test. Key findings are that for a successful trial it is essential to document the procedures that form the basis for the alternative, to use an independent third party to audit, and to agree the format of the audits and reporting systems.

7.3 A rigorous and reliable method of recording and logging trial data is also critical so that all data can be crosschecked and confirmed as true. The trial data logging system must be validated before the trial commences. As shown by this trial (see Appendix 2), spurious data that would have affected the trial outcome was manually recorded in the last days of the trial. However, by examining the automatically logged batch files the human error was revealed and the incorrectly reported trial data corrected accordingly.

7.4 The trial also showed that the 'alternative system' was as reliable as the water bath test at identifying pressure stable and leaking aerosols. During the Trial no aerosols that had been subjected to the 'alternative system' burst in the hot water bath and only 115 leaking aerosols were identified from the 12,089,148 produced aerosols. The data also shows that no consecutive leakers were produced. The 11 leaking aerosols not identified by the alternative system and the 8 leaking aerosols not identified by the water bath do not present a significant risk to the consumer or the distribution system.

7.5 The trial results also show that the quality of empty cans supplied by the can manufacturer to the aerosol filler can be improved if the QA procedures adopted in the 'alternative system' are adopted. Some cans filled in the trial period were from old stock (i.e. predated the trial) and were rejected by the water bath because they were leaking from the can seam. These cans were not included in the trial because they had not passed through the can makers' QA and testing procedures as demanded by the alternative system. However, their performance when compared to the cans supplied for the trial is indicative that the pressure/leak detectors installed at the can suppliers resulted in a better quality can being supplied to the aerosol filler.

7.6 With online data recording then a continuous improvement programme is possible. From the summary results in Section 6.1 it can be seen that the quality assurance built into the alternative system generated very few leakers.

8. CONCLUSION

The premise for the validity of an 'alternative system' to the hot water bath test must be based on an assessment of the residual risk to an aerosol user. Any risk associated with the use of an aerosol must be no greater regardless of whether the aerosol was manufactured using the traditional water bath or an alternative system.

As discussed in Section 2 of this report, the potential risk associated with aerosol usage could be realised by one of two scenarios.

a) A bursting aerosol results in a projectile or the sudden release of contents creating a significant flammable atmosphere which could result in a flash fire or explosion.

b) An aerosol developing a significant leak in a poorly ventilated place thus generating a significant flammable atmosphere.

With regards to (a) not one of the aerosol cans tested by the alternative system ruptured when passed through the water bath. It can therefore be concluded that the proposed alternative system is a valid method for assuring aerosols are pressure stable.

With regards to (b) any water bath alternative system shall be as good as the water bath in identifying aerosols that leak. The alternative system and the water bath tested 12 089 148 aerosols over 12 months during which 414 batch orders were processed and 115 aerosols were identified as leaking aerosols The trial demonstrated that the alternative is as good as the traditional water bath at identifying leaking aerosols. Of the leaking aerosols, 107 were identified by the water bath as leaking and 104 were identified by the alternative method as leaking. This does not represent a significant difference and in June 2003 the alternative method identified 14 leaking aerosols, the water bath identified 12 leaking aerosols.

It should be noted that the quality assurance methods employed by the alternative system improved the quality of can delivered to the filler. Some cans from old stock and cans from other can manufacturers did leak from the body when used on the filling line, whereas cans from the suppliers which had been pressure tested pre-delivery, in accordance with the alternative method did not leak from the body nor burst.

APPENDIX 1

DESCRIPTION OF THE TRIAL

A1.1 The Approach

The Water Bath Alternative System selected for the trial is an integrated package involving the can manufacturer, valve manufacturer and the aerosol filler. It is based on the following key principles:

i) High level quality assurance procedures in place for the valve and can manufacture to ensure only high quality components are used by the filler.
ii) A pressure test for all empty aerosol cans by the can manufacturer to a pressure equal to or in excess of the maximum expected in the filled aerosols at 50°C.
iii) High level quality assurance in place during aerosol handling and filling to ensure that only high quality aerosols are produced that include:
    a) checks on setting and maintaining the correct valve crimp dimensions.
    b) in-line check-weigher system to ensure overfilled aerosols are rejected.
iv) A micro-leak detector on the filling line to test the valve and valve crimp of all filled aerosols for leaks.

A consortium consisting of one valve supplier; two metal can suppliers and Wella AG (Wella) - aerosol filler, was created for the trial. Burgoyne Consultants Ltd (BCL) was appointed as independent verifier to validate the trail.

The alternative system was set up so that all aerosols tested by the alternative system were immediately conveyed down the line to be tested by a water bath. All aerosols rejected by either or both systems were ink marked to identify which system had rejected the can and this data was automatically recorded by a computer data logging system. Every rejected aerosol was tested manually in a laboratory water bath to identify if the aerosol was truly leaking and from what point. Aerosols found to be not leaking were returned to the filling line prior to the microleak detector at an appropriate time during the production run. Aerosols found to be leaking were retained for further investigation. Each manual test was recorded.

A1.2 Quality Assurance Requirements

BCL visited the manufacturing facilities of the can suppliers, the valve supplier and aerosol filler prior to the start of the trial to carry out a quality audit. These quality audits were based upon ISO9001 and checked that the quality systems in place covered the following points:

- The company had a quality manual in place and carried out internal audits to verify adherence to its systems.
- Components were identifiable so that they could be traced back to the manufacturer's batch number.
- All quality documents were issued under the authority of the Quality Assurance manager. There was stringent document control which assures that procedures were in accordance with the correct document revision: unauthorized changes to procedures did not occur and all production quality documentation was collated and retained for at least five years.
- The filler received the supplier certification for the components before they were released to production. The filler carried out periodic inspections of their suppliers for compliance with agreed quality procedures.
- All test equipment that is critical to quality was identified and routinely calibrated. For example the measurement apparatus for determining the crimp dimensions, and the dip tube length, were each identified with a unique number, and after calibration a label was attached to the measurement apparatus that showed the date when its next calibration is due. The operator could therefore carry out inspections and measurement with test equipment known to have been calibrated and not to have exceeded its next calibration date.
- If too many units were ejected from the filling line as non-conforming, then production

was stopped and the batch quarantined. The management inspected the quarantined stock and decide if it is satisfactory and what corrective action was required.

- Minor corrective actions carried out by the production team under appropriate supervision, were recorded. Production management reviewed minor corrective actions. Major corrective actions were authorised and recorded by the production management.
- Legible quality records were in place.
- During assembly, in-process inspection and testing was in place to ensure adherence to the product specifications.
- The final product underwent a final inspection and testing protocol.
- Procedures ensured that there should be no damage to final product.
- Product for dispatch was adequately packaged so as to prevent damage while in-transit. The package was adequately labelled so that the contents could be readily identified and complied with transport regulations.

The audits identified a number of critical issues for the trial and these were addressed before the trial of the alternative system commenced. The principal issues addressed were:

i) The product may seal very small holes and some aerosols may appear to be leaking if they are carrying trapped air, e.g. under the crimp. Therefore, a manual water bath was placed immediately adjacent to the filling line, so that rejected aerosols could be tested as soon as possible after they were ejected to check that they were really leaking.
ii) The can maker pressure tested every can to two thirds of the can deformation pressure rating and tested for a leak rate of 3.3×10^{-2}mbar.l.s^{-1}.
iii) To generate data that allowed for a comparative assessment of the water bath and the proposed alternative.

A1.3 Can Manufacture

Metal aerosol cans from two suppliers were used for the trial, both the suppliers had stringent procedures with the necessary documentation control in place that satisfied the quality assurance requirements of A1.2. Delivery notes and pallet labels provide a unique manufacture number for the can which may be used to identify when the can was made and to retrieve the production record sheets.

The can manufacturers pressure tested each completed can using a pressure test unit by the following procedure. Each aerosol can was placed inside a rotating chamber of the pressure tester unit. As the trial used 15 barg cans, the can was pressurised to 10 barg and if a leak occurred, the subsequent increase of pressure in the chamber was identified and the can was rejected. The can was initially supported on a disc that lifts it into a cylindrical chamber with the disc sealing the chamber by forming the chamber floor. The curled top was then clamped and the can lifted off the chamber floor before it is pressurized to 10 barg. It is critical that the can was only supported at the top end for the test to be meaningful. If the can was supported at the bottom and top then the additional support would strengthen the can and so the pressure test may not reveal weak cans. The pressure test unit has several rotating chambers. A functionality test was carried out on each chamber prior to each test to ensure it will detect a pressure increase and the performance of each chamber was continuously monitored to ensure no one chamber was acting erroneously.

A1.4 Valve Supplier

The valve supplier had satisfactory procedures with the necessary documentation control in place that satisfied the quality assurance requirements of A1.2. Delivery notes and pallet labels provide a unique manufacture number for the valve which can be used to identify when it was made and to retrieve the production record sheets.

A1.5 Aerosol Filler

The filler had satisfactory procedures with the necessary documentation control in place that satisfied the quality assurance requirements of A1.2. Production line 31 was dedicated for the Water Bath Alternative Trial. This is a conventional aerosol can filling line comprising:

Empty can depalletisation,
Product base filler,
Valve placer,
Crimper,
Gasser,
Check weigher,
Valve and crimp leak detector,
Water bath,
Buttoner,
Capper,
Shrinkwrapper

The valve and crimp leak detector was a new unit and installed at the filler for this trial. Each filled aerosol was placed onto one of fifteen rotating heads of the leak detector. Each head covers the valve and will detect a leak from the valve crimp or the valve itself. At the start of a product change-over which requires the crimping head to be reset, the integrity of the new crimp setting was proven by testing an aerosol in a laboratory manual water bath.

The aerosol then passes through a water bath unit in the normal manner. The water bath had an automatic leak detection system, using a differential pressure method. Should the water bath detect a leak in a filled aerosol, systems were in place to identify the offending aerosol and to automatically reject it from the production line, into a waste bin.

In addition, an inkjet marker was installed after the leak detector unit to mark all aerosols detected as leaking. In this way it was possible to tell whether rejected aerosols have been detected by the leak detector as well as the water bath. A computer recorded the status of every aerosol on the production line using the coding system defined below.

0	No leakage detected
1	Leak detected by leak detector unit only
2	Leak detected by Water bath unit only
3	Leak detected by both units.

All aerosols identified as leaking by the water bath or the pressure test unit but with no obvious visual defect were pressure tested in a manual water bath sited adjacent to the line to establish whether there was in fact a leak and, if so, the cause of the leak.

APPENDIX 2

TRIAL AUDITS

This Appendix provides a summary record of the audits and visits carried out by the Burgoyne Consultants Limited (BCL) as part of the verification process. The summaries below are not stand-alone statements but are provided to give an overview of the audit work carried out during the trial. For full details, the relevant audit reports should be consulted.

A2.1 June 2001 - BCL Report 5/244310/SM-B Rev.0

The valve supplier and the two can manufacturers were audited to ISO9001 standards to ascertain that they were producing quality goods and to confirm that their components were traceable and that suitable and sufficient testing procedures were in place. The audits concluded that the component suppliers were compliant with the alternative method requirements.

The audit reviewed the water bath trial at Wella to ensure procedures were in place and meaningful results were being generated. This audit required various actions to be implemented before the trial commenced. The key actions were to ensure that:

i) All rejected cans were identified by an ink jet mark that clearly indicated which system had rejected the can.
ii) An accurate and reliable computer logging system was in place
iii) All rejected cans were inspected, tested and recorded.
iv) Copies of trial documentation were submitted to the consultants.
v) A manual laboratory water bath was placed adjacent to the water bath so that aerosols could be tested as quickly as possible to identify true leakers. (Not all aerosols rejected from the water bath are true leakers e.g. entrapped bubbles might cause a can to be rejected.).

A2.2 September 2001 – BCL Report 5/296395/CPM-A Rev.0

This review confirmed that audit actions from June 2001 were completed. During trial commissioning, a few aerosol cans supplied from can manufacturer A were identified as leakers. Can manufacturer A therefore installed a new can leak detector that was more accurate and reliable.

A2.3 November 2002 – BCL Report 5/244310/CPM-C Rev.0 BCL Site visit to Wella

This review focused on the trial documentation to ensure that procedures were in place. To confirm adherence the consultants carried out random specific audits on several batch records and rejected aerosols. It was concluded that procedures were being followed.

A2.4 February 2003 – BCL 5/244310/CPM BCL Site visit to can manufacturer A

The consultants reviewed the operation of the new can leak detector and the quality procedures. The operations were found to be satisfactory.

A2.5 April 2003 – BCL 5/244310/CPM BCL Site visit to Wella

The consultants visited the filler to review the operation of the alternative test method and compare documentation submitted with the original trial documentation. No discrepancies between the original and copied documentation were found.

A2.6 September 2003 –Wella Report Technical report water bath ref - FEH-La-gr, Wella visit to BCL

The trial ran from July 2002 to June 2003. Throughout the trial the consultants produced monthly reports based on submitted trial data. The trial data for June 2003 was markedly different with 11 leakers being identified by the water bath only. If true the June figures would skew the results of the 12 month trial such that it would have been only possible to conclude that the proposed alternative system had failed. BCL therefore requested Wella to cross check the declared results with the original computer logged batch data for the trial and the above technical report was submitted to the consultants. The trial has generated manual and automated records. Every aerosol that passes through line 31 was identified and logged on a spreadsheet as a 0 for ‘No leakage detected’, 1 for ‘Leak detected by leak detector unit only’, 2 for ‘Leak detected by Water bath unit only’ and a 3 for ’Leak detected by both units’. These numbers are logged in a sequential order for each batch so that it is possible, for example, to check which system had rejected the 25th aerosol on a given batch. The computer logging system was validated at the start of the trial. The original batch spread sheet was therefore checked to determine which system had rejected the aerosols.

Investigation of the 11 leakers in question, found that 4 leakers were found to be cans not sourced according to the requirements of the ‘alternative system’ and therefore not part of the trial. 6 leakers were detected by the ‘alternative system’ only and 1 leaker by both methods. The reason for the incorrect manual reporting was human error, with 6 of the questioned aerosols being identified as leaking by the water bath only during an output of 1½ hours in one night shift. The findings were recorded in the ‘Technical report water bath,’ September 2003, ref - FEH-La-gr. On receipt of the report, the consultants revised the June results accordingly.

APPENDIX 3

SUMMARY OF TRIAL DATA

A3.1 Production Data

The table below provides a daily summary of the trial results and is sourced from data provided by the daily computer consolidation sheets and the manual laboratory evaluation sheet.

DATE	Can Material	Product	Can Supplier	Fill (ml)	Number of Aerosols Filled	Number Confirmed Leaking
03/07/02	Tinplate Steel	Hair Spray	B	300	109 725	
05/07/02	Tinplate Steel	Hair Spray	B	300	106 125	1
07/07/02	Tinplate Steel	Hair Spray	A	500	22 440	1
09/07/02	Tinplate Steel	Hair Spray	A	500	10 530	
18/07/07	Tinplate Steel	Hair Spray	A	400	7 005	1
19/07/02	Tinplate Steel	Hair Spray	A	400	16 980	
20/07/02	Tinplate Steel	Hair Spray	B	300	89 235	
22/07/02	Tinplate Steel	Hair Spray	B	300	56 955	
23/07/02	Tinplate Steel	Hair Spray	B	300	145 353	
24/07/02	Tinplate Steel	Hair Spray	B	300	175 890	
25/07/02	Tinplate Steel	Hair Spray	B	300	144 495	
26/07/02	Tinplate Steel	Hair Spray	B	300	106 215	1
27/07/02	Tinplate Steel	Hair Spray	B	300	103 935	
29/07/02	Tinplate Steel	Hair Spray	B	300	80 790	
30/07/02	Tinplate Steel	Hair Spray	B	300	38 295	
31/07/02	Tinplate Steel	Hair Spray	A	500	81 585	1
JULY 2002 TOTAL PRODUCTION OF AEROSOLS					**1 295 553**	**5**
01/08/02	Tinplate Steel	Hair Spray	A	500	25 650	
02/08/02	Tinplate Steel	Hair Spray	A	300/400	22 155	
05/08/02	Tinplate Steel	Hair Spray	A	300	9 975	
19/08/02	Tinplate Steel	Hair Spray	A	500	9 705	1
20/08/02	Tinplate Steel	Hair Spray	A	500	57 975	3
21/08/02	Tinplate Steel	Hair Spray	A	500	74 940	
22/08/02	Tinplate Steel	Hair Spray	A	500	73 635	1
23/08/02	Tinplate Steel	Hair Spray	B	300	125 595	
24/08/02	Tinplate Steel	Hair Spray	B	300	33 825	
25/08/02	Tinplate Steel	Hair Spray	B	300	48 885	
26/08/02	Tinplate Steel	Hair Spray	B	300	66 775	
27/08/02	Tinplate Steel	Hair Spray	B	300	124 530	1
28/08/02	Tinplate Steel	Hair Spray	B	300	138 600	
29/08/02	Tinplate Steel	Hair Spray	B	300	152 760	2
30/08/02	Tinplate Steel	Hair Spray	B	300	170 995	
31/08/02	Tinplate Steel	Hair Spray	B	300	12 585	
AUGUST 2002 TOTAL PRODUCTION OF AEROSOLS					**1 148 585**	**8**
05/09/02	Tinplate Steel	Hair Spray	A	400	24 945	4
06/09/02	Tinplate Steel	Hair Spray	A	400	118 155	
07/09/02	Tinplate Steel	Hair Spray	A	400	34 230	
19/09/02	Tinplate Steel	Hair Spray	A	400	39 660	
20/09/02	Tinplate Steel	Hair Spray	A	400	81 135	8
23/09/02	Tinplate Steel	Hair Spray	A	400	66 330	5
27/09/02	Tinplate Steel	Hair Spray	A	500	53 040	

DATE	Can Material	Product	Can Supplier	Fill (ml)	Number of Aerosols Filled	Number Confirmed Leaking
30/09/02	Tinplate Steel	Hair Spray	A	500	15 000	
SEPTEMBER 2002 TOTAL PRODUCTION OF AEROSOLS					**432 495**	**17**
01/10/02	Tinplate Steel	Hair Spray	A	500	51 360	
02/10/02	Tinplate Steel	Hair Spray	A	400	80 055	
07/10/02	Tinplate Steel	Hair Spray	A	400	94 170	1
08/10/02	Tinplate Steel	Hair Spray	B	300	101 730	
09/10/02	Tinplate Steel	Hair Spray	B	300	128 865	
10/10/02	Tinplate Steel	Hair Spray	B	300	35 490	
25/10/02	Tinplate Steel	Hair Spray	A	500	51 990	
28/10/02	Tinplate Steel	Hair Spray	A	500	52 725	
29/10/02	Tinplate Steel	Hair Spray	A	500	55 785	
30/10/02	Tinplate Steel	Hair Spray	A	500	66 510	
31/10/02	Tinplate Steel	Hair Spray	A	400	125 130	6
OCTOBER 2002 TOTAL PRODUCTION OF AEROSOLS					**843 810**	**7**
01/11/02	Tinplate Steel	Hair Spray	B	300	54 300	
02/11/02	Tinplate Steel	Hair Spray	B	300	84 255	
04/11/02	Tinplate Steel	Hair Spray	B	300	174 465	
05/11/02	Tinplate Steel	Hair Spray	B	300	159 915	1
06/11/02	Tinplate Steel	Hair Spray	B	300	164 250	
07/11/02	Tinplate Steel	Hair Spray	B	300	136 080	
08/11/02	Tinplate Steel	Hair Spray	B	300	189 735	1
09/11/02	Tinplate Steel	Hair Spray	B	300	90 870	
11/11/02	Tinplate Steel	Hair Spray	B	300	156 585	
20/11/02	Tinplate Steel	Hair Spray	A	400	40 455	
21/11/02	Tinplate Steel	Hair Spray	A	400	110 355	1
22/11/02	Tinplate Steel	Hair Spray	A	500	83 250	
23/11/02	Tinplate Steel	Hair Spray	A	500	74 475	1
25/11/02	Tinplate Steel	Hair Spray	A	400	120 765	
26/11/02	Tinplate Steel	Hair Spray	A	400	167 535	
27/11/02	Tinplate Steel	Hair Spray	A	300	35 115	
28/11/02	Tinplate Steel	Hair Spray	A	300	4 170	
29/11/02	Tinplate Steel	Hair Spray	A	300	720	
NOVEMBER 2002 TOTAL PRODUCTION OF AEROSOLS					**1 847 295**	**4**
02/12/02	Tinplate Steel	Hair Spray	B	300	104 790	
03/12/02	Tinplate Steel	Hair Spray	B	300	162 330	
04/12/02	Tinplate Steel	Hair Spray	B	300	89 895	
05/12/02	Tinplate Steel	Hair Spray	B	300	22 395	
06/12/02	Tinplate Steel	Hair Spray	B	300	168 060	
07/12/02	Tinplate Steel	Hair Spray	B	300	55 170	
09/12/02	Tinplate Steel	Hair Spray	B	300	116 160	
17/12/02	Tinplate Steel	Hair Spray	A	400	57 450	
18/12/07	Tinplate Steel	Hair Spray	A	400	44 655	
19/12/02	Tinplate Steel	Hair Spray	A	500	57 675	

DATE	Can Material	Product	Can Supplier	Fill (ml)	Number of Aerosols Filled	Number Confirmed Leaking
DECEMBER 2002 TOTAL PRODUCTION OF AEROSOLS					**878 580**	**0**
07/01/03	Tinplate Steel	Hair Spray	B	300	125 715	
08/01/03	Tinplate Steel	Hair Spray	B	300	90 240	
09/01/03	Tinplate Steel	Hair Spray	A	500	94 680	
10/01/03	Tinplate Steel	Hair Spray	A	500	47 685	
20/01/03	Tinplate Steel	Hair Spray	A	400	19 725	
21/01/03	Tinplate Steel	Hair Spray	A	400	116 805	2
22/01/03	Tinplate Steel	Hair Spray	A	500	115 275	3
23/01/03	Tinplate Steel	Hair Spray	A	500	92 985	
28/01/03	Tinplate Steel	Hair Spray	A	400	10 080	
29/01/03	Tinplate Steel	Hair Spray	A	400	166 515	2
30/01/03	Tinplate Steel	Hair Spray	A	400	26 280	
31/01/03	Tinplate Steel	Hair Spray	A	400	175 235	
JANUARY 2003 TOTAL PRODUCTION OF AEROSOLS					**1 081 220**	**7**
01/02/03	Tinplate Steel	Hair Spray	B	300	49 560	
03/02/03	Tinplate Steel	Hair Spray	B	300	119 040	
04/02/03	Tinplate Steel	Hair Spray	B	300	196 800	
05/02/03	Tinplate Steel	Hair Spray	B	300	172 080	
06/02/03	Tinplate Steel	Hair Spray	B	300	213 885	
07/02/03	Tinplate Steel	Hair Spray	A	500	25 305	1
18/02/07	Tinplate Steel	Hair Spray	A	400	50 145	1
19/02/03	Tinplate Steel	Hair Spray	A	400	45 615	1
20/02/03	Tinplate Steel	Hair Spray	A	500	54 165	1
21/02/03	Tinplate Steel	Hair Spray	A	500	23 490	
22/02/03	Tinplate Steel	Hair Spray	A	500	39 195	3
24/02/03	Tinplate Steel	Hair Spray	A	500	18 540	
25/02/03	Tinplate Steel	Hair Spray	B	300	26 685	
26/02/03	Tinplate Steel	Hair Spray	B	300	48 120	
27/02/03	Tinplate Steel	Hair Spray	B	300	58 035	
28/02/03	Tinplate Steel	Hair Spray	B	300	53 295	
FEBRUARY 2003 TOTAL PRODUCTION OF AEROSOLS					**1 193 955**	**7**
04/03/03	Tinplate Steel	Hair Spray	B	300	79 725	
05/03/03	Tinplate Steel	Hair Spray	B	300	176 055	
06/03/03	Tinplate Steel	Hair Spray	B	300	167 864	
07/03/03	Tinplate Steel	Hair Spray	B	300	70 860	
13/03/03	Tinplate Steel	Hair Spray	B	200	110 520	3
14/03/03	Tinplate Steel	Hair Spray	B	200	62 100	4
MARCH 2003 TOTAL PRODUCTION OF AEROSOLS					**667 124**	**7**
25/04/03	Tinplate Steel	Hair Spray	A	500	500	
28/04/03	Tinplate Steel	Hair Spray	A	500	500	1
29/04/03	Tinplate Steel	Hair Spray	B	400	66 480	
30/04/03	Tinplate Steel	Hair Spray	B	400	65 850	

DATE	Can Material	Product	Can Supplier	Fill (ml)	Number of Aerosols Filled	Number Confirmed Leaking
APRIL 2003 TOTAL PRODUCTION OF AEROSOLS					**188 145**	**1**
03/05/03	Tinplate Steel	Hair Spray	A	400	96 915	
05/05/03	Tinplate Steel	Hair Spray	A	400	111 330	
06/05/03	Tinplate Steel	Hair Spray	A	400	144 360	
07/05/03	Tinplate Steel	Hair Spray	B	300	124 455	
08/05/03	Tinplate Steel	Hair Spray	B	300	173 220	1
09/05/03	Tinplate Steel	Hair Spray	B	300	190 800	
12/05/03	Tinplate Steel	Hair Spray	B	300	91 935	2
13/05/03	Tinplate Steel	Hair Spray	B	300	58 215	
14/05/03	Tinplate Steel	Hair Spray	B	200	89 940	28
15/05/03	Tinplate Steel	Hair Spray	B	200	62 865	3
27/05/03	Tinplate Steel	Hair Spray	A	500	29 190	
MAY 2003 TOTAL PRODUCTION OF AEROSOLS					**1 173 225**	**34**
02/06/03	Tinplate Steel	Hair Spray	B	400	81 300	
03/06/03	Tinplate Steel	Hair Spray	B	300	46 680	
04/06/03	Tinplate Steel	Hair Spray	B	300	156 705	1
05/06/03	Tinplate Steel	Hair Spray	B	300	235 080	
06/06/03	Tinplate Steel	Hair Spray	B	300	135 450	
07/06/03	Tinplate Steel	Hair Spray	B	300	5 640	
10/06/03	Tinplate Steel	Hair Spray	B	300	66 225	
17/06/03	Tinplate Steel	Hair Spray	A	500	16 920	
18/02/07	Tinplate Steel	Hair Spray	A	500	92 821	1
19/06/03	Tinplate Steel	Hair Spray	A	400	30 990	1
20/06/03	Tinplate Steel	Hair Spray	A	400	49 155	4
23/06/03	Tinplate Steel	Hair Spray	A	400	68 685	
26/06/03	Tinplate Steel	Hair Spray	B	300	124 500	11
27/06/03	Tinplate Steel	Hair Spray	B	300	67 515	
28/06/03	Tinplate Steel	Hair Spray	B	300	78 740	
30/06/03	Tinplate Steel	Hair Spray	B	300	82 755	
JUNE 2003 TOTAL PRODUCTION OF AEROSOLS					**1 339 161**	**8**
TOTAL AEROSOLS FOR TRIAL					**12 089 148**	**115**

A3.2 Assessment of Reason For Leaks

All aerosols rejected from the production line were tested in the manual water bath. The table below identifies each leaking can and/or valve and when known the reason for its leak.

Reject Nos	Date	Location of Leak	Identified By	Reason
1	5/07/02	Valve	LD &WB	(valve bx number 25150403001)
2	7/07/02	Valve	LD &WB	(valve bx number 25150403001)
3	18/07/02	Valve	LD &WB	(valve bx number 25150200200)
4	26/07/02	Valve	LD & WB	No manual water bath sheet giving valve number
5	31/07/02	Valve	LD & WB	(valve bx number 25151107200)
6	19/08/02	Valve	LD & WB	(valve bx number 25151101001)
7	20/08/02	Valve crimp	WB & LD	(valve bx number 73781120100) (can bx number 5779700060)
8	20/08/02	Valve crimp	WB & LD	(valve bx number 73781120100) (can bx number 5779700060)
9	20/08/02	Valve crimp	WB & LD	(valve bx number 73781120100) (can bx number 5779700060)
10	22/08/02	Valve crimp	WB & LD	(valve bx number 25151107203) (can bx number 35060000199)
11	27/08/02	Top Seam	WB	(can bx number 41660000103) Aerosol returned to Can manufacturer B where on re testing by the Leak Detector Unit it was rejected.
12	29/08/02	Valve	LD	(valve bx number 25150403001)
13	29/08/02	Top Triple Point	WB	(can bx number 41660000003) Aerosol returned to Can manufacturer B where on re testing by the Leak Detector Unit it was rejected.
14	06/09/02	Valve	LD&WB	(valve bx number 25151001006) Defect pin in valve cup as supplied by manufacturer.
15	06/09/02	Valve	WB	(valve bx number 25151001006) Defect pin in valve cup as supplied by manufacturer.
16	06/09/02	Valve Crimp	LD + WB	(valve bx number 25151001006) (can bx number 41778100205)
17	06/09/02	Valve Crimp	LD	(valve bx number 25151001006) (can bx number 41778100205)
18	20/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
19	20/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
20	20/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
21	20/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
22	20/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
23	20/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
24	20/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
25	20/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
26	23/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
27	23/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
28	23/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
29	23/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
30	23/09/02	Valve	LD&WB	No manual water bath sheet giving valve number
31	07/10/02	Valve	LD & WB	No manual water bath sheet giving valve number
32	31/10/02	Valve	WB	(valve bx number 25151001006)
33	31/10/02	Valve	LD & WB	(valve bx number 25151001006)
34	31/10/02	Valve	LD & WB	(valve bx number 25151001006)
35	31/10/02	Valve	LD & WB	(valve bx number 25151001006)
36	31/10/02	Valve	LD & WB	(valve bx number 25151001006)
37	31/10/02	Valve	LD & WB	(valve bx number 25151001006)
38	05/11/02	Valve	LD & WB	(valve bx number 25150403001)
39	08/11/02	Valve Crimp	LD & WB	(can bx number 4166000203) (valve bx number 25150403001)
40	21/11/02	Valve	LD & WB	(valve bx number 25151001006)
41	23/11/02	Valve	LD & WB	(valve bx number 25151007200)
42	21/01/03	Valve	LD & WB	(valve bx number 25151001006)
43	21/01/03	Valve & Valve crimp	WB	(valve bx number 25151001006) (can bx number 41778100205)
44	22/01/03	Valve	LD & WB	(valve bx number 25151001006)
45	22/01/03	Valve	LD & WB	(valve bx number 25151001006)
46	22/01/03	Valve	LD & WB	(valve bx number 25151001006)
47	29/01/03	Valve Crimp	LD &WB	(valve bx number 25151001006)
48	29/01/03	Valve	LD &WB	(valve bx number 25151001006)
49	07/02/03	Valve crimp	LD & WB	(can bx number 57737000160)
50	18/02/07	Valve	LD & WB	(valve bx number 25151001006)
51	19/02/03	Valve	LD & WB	(valve bx number 25151001006)

Reject Nos	Date	Location of Leak	Identified By	Reason
52	20/02/03	Valve	LD & WB	(valve bx number 25151107203)
53	22/02/03	Valve	LD & WB	(valve bx number 25151107200)
54	22/02/03	Valve	LD & WB	(valve bx number 25151107200)
55	22/02/03	Valve	LD & WB	(valve bx number 25151107200)
56	13/03/03	Valve	LD & WB	(valve bx number 25151001002)
57	13/03/03	Valve	LD & WB	(valve bx number 25151001002)
58	13/03/03	Valve	WB	(valve bx number 25151001002)
59	14/3/03	Valve	LD & WB	(valve bx number 25151001002)
60	14/3/03	Valve	LD & WB	(valve bx number 25151001002)
61	14/3/03	Valve Crimp	LD & WB	(can bx number 40921000277)
62	14/3/03	Top Seam	WB	(can bx number 40921000277)
63	28/04/03	Valve	LD & WB	Valve Batch nos 25151007200
64	08/05/03	Valve	LD & WB	(valve bx number 25150403001)
65	12/05/03	Valve	LD & WB	No evaluation sheet
66	12/05/03	Valve	LD & WB	No evaluation sheet
67	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
68	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
69	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
70	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
71	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
72	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
73	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
74	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
75	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
76	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
77	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
78	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
79	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
80	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
81	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
82	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
83	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
84	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
85	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
86	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
87	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
88	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
89	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
90	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
91	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
92	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
93	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
94	14/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
95	15/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
96	15/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
97	15/05/03	Valve Crimp	LD & WB	(can bx number 4921000477) (valve bx number 25151001002)
98	05/06/03	Valve	WB & LD	No evaluation sheet
99	18/06/03	Valve Crimp	WB & LD	(can bx number 41778100205) (valve bx number 25151001006)
100	20//06/03	Valve	WB & LD	(valve bx number 25151001006)
101	23//06/03	Valve Crimp	LD	No evaluation sheet
102	23//06/03	Valve Crimp	WB & LD	No evaluation sheet
103	23//06/03	Valve Crimp	WB	No evaluation sheet
104	23//06/03	Valve Crimp	WB	No evaluation sheet
105	26//06/03	Valve	WB	No evaluation sheet
106	26//06/03	Valve	LD	No evaluation sheet
106	26//06/03	Valve	WB	No evaluation sheet
108	26//06/03	Valve	LD	No evaluation sheet
109	26//06/03	Valve	LD	No evaluation sheet
110	26//06/03	Valve	LD	No evaluation sheet
111	26//06/03	Valve	LD	No evaluation sheet
112	26//06/03	Valve	LD	No evaluation sheet
113	26//06/03	Valve	WB & LD	No evaluation sheet
114	26//06/03	Valve	WB & LD	No evaluation sheet
115	26//06/03	Valve	WB & LD	No evaluation sheet