Figure 11.7a. COSTS OF POOR QUALITY AND PRODUCTIVITY: Consumer Goods

EM9024: Maclean's Magazine, February 26, 1990, page 34

Perrier issues a worldwide recall order

It was a leading symbol of the age. Throughout the 1980s, Perrier, the sparkling mineral water originating from a spring in the south of France, was often the beverage of choice for health-conscious baby boomers. But the odourless and virtually tasteless liquid became tainted with scandal last week when Paris-based Source Perrier SA announced that it would withdraw and destroy up to 160 million bottles of its bubbly product around the world. The company's problems began on Feb. 10 after Health and Welfare Canada and the U.S. Food and Drug Administration (FDA) said that food inspectors in North Carolina had found, in random tests, 13 bottles contaminated with traces of benzene, a clear, naturally occurring gas that has been linked to cancer in tests with laboratory animals. Initially, the recall was confined to 72 million bottles in Canada and the United States, but when traces of benzene also showed up in Perrier in Europe, Perrier chairman Gustave Leven announced the worldwide withdrawal. Said Leven: "Half measures were not possible."

The recall will cost Perrier more than $40 million. And the company, which boasts in its advertisements that "It's perfect, it's Perrier," will launch a massive publicity campaign to quickly convince consumers that its sparkling water is indeed perfect again. If not, Perrier, which dominates the competitive bottled-water market and registered net profits of $86 million for the first six months of 1989, could lose its lead to its aggressive competition. Said Al Ries, chairman of Trout and Ries Inc., a marketing strategy firm in Greenwich, Conn.: "When a brand is consumed daily, out of sight is out of mind." And Frank de Vries, president of the Toronto-based Perrier Group of Canada Inc., said details of the ad campaign, which were still being worked out, would be announced once the company had a firm date for new shipments of benzene-free Perrier.

Perrier, which sells one billion bottles worldwide annually, initiated the recall after testing in the United States indicated that there were between 12.3 and 19.9 parts per billion of benzene in some samples. Both the FDA and Health and Welfare prohibit more than five parts per billion. Frederick Zimmer, managing director of Source Perrier, said that the problem occurred when filters, which are normally replaced every six weeks at the Perrier spring, were inadvertantly not changed for four months. Production of nearly six million bottles a day resumed after the filters were changed, and company officials said that the French ministry of health has certified that the spring is not contaminated. The spring, in the small town of Vergèze, was formed almost 140 million years ago, and its natural carbonation resulted from ancient volcanic eruptions.

At week's end, Perrier shares closed at $324, after dropping down to $298 at midweek from $357 before the recall announcement. But, for the self-declared perfect company, the biggest financial gamble lies ahead, as it spends millions of dollars to convince consumers that their favourite liquid status symbol is still safe.

BARBARA WICKENS *with correspondents' reports*

1. About half way down the right-hand column of the *Maclean's* article EM9024 reprinted above, Frederick Zimmer is quoted as having said that the benzene contamination was a result of .... *filters, which are normally replaced every six weeks, (being) inadvertently not changed for four months.* Indicate briefly the quality assurance implication(s) of this statement.

2. In addition to the cost (430 million francs, given in the article EM9035 reprinted at the right) of withdrawing and destroying contaminated product worldwide, outline the *other* major costs that Perrier incurred as a result of the problem.
   - Which of these extra costs is the most difficult to quantify? Explain briefly.
   - Approximately what fraction of a year's profit is the *total* of all the extra costs likely to represent? Briefly justify your answer.
   - If you were to be retained by Perrier as a quality assurance consultant, what recommendations would you make to help the company to avoid a repetition of the problem.

3. Near the middle of the first paragraph of the *Maclean's* article EM9024 reprinted above, there is a reference to .... *random tests* ..... Explain briefly the meaning of the word *random* in this context.

4. From the perspective of an interested reader of the two articles reprinted in this Figure 11.7a, compare critically the wording of the two references to the carcinogenic properties of benzene.

EM9035: The Globe and Mail, May 11, 1990, page B17

Product removal costs cut profit, Perrier says

Reuter

PARIS

Source Perrier SA of France says it has set aside a reserve of 430 million francs ($91-million) to cover the cost of removing its bubbly mineral water from shelves around the world following a health scare in February.

The company said the provision reduced its profit for 1989 to 266 million francs from 1.03 billion francs in 1988.

The profit picture was distorted in both years by capital gains that Perrier, a diversified company with interests ranging from cheese to radiators, made on the sale of investments. These came to 254 million francs in 1989 and 857 million francs in 1988.

The mineral water giant was forced to recall about 160 million bottles in February after minute traces of benzene, a naturally occurring solvent that can cause cancer, were discovered. The contamination was traced to a faulty filter at the Vergèze bottling plant in southern France.

Figure 11.7b. COSTS OF POOR QUALITY AND PRODUCTIVITY: Consumer Goods

EM9020: Toronto Star, February 10, 1990, pages G1 and G3

CONDOMS

Lab tests reveal some flaws

In a small sample, two brands failed to meet some government standards

By Kim Zarzour
TORONTO STAR

A laboratory test of a small sample has turned up flaws in some brands of condoms currently available at many of Canada's colleges and universities.

The Star commissioned a research firm to test five condom brands – Ramses Sensitol, Trojan-enz, Protex, Beyond and LifeStyles – to see how they stacked up under the requirements of Health and Welfare Canada.

In a critical test of the point at which they burst, a significant number of Protex and Ramses Sensitol failed to meet federal standards. In tests for leakage, the Protex brand showed some flaws.

It was not an exhaustive study; it was a laboratory analysis of 10 to 15 of each of the brands, purchased much as a consumer might buy them. Under federal testing procedures, a greater number would have to be tested before any conclusions could be drawn.

Protex is sold in vending machines at many universities and colleges across Canada as well as in bars and strip clubs; Ramses is one of the best-selling brands in drug stores. Protex is also one of the main brands being considered for use in the new vending machines in Toronto public schools.

The 14 Protex condoms used in the Star tests were purchased in a women's washroom at Ryerson Polytechnical Institute. The Ramses were bought in a Toronto drug store.

In tests performed by Retail Research Laboratories, Protex was the only one that did not conform to length requirements under the federal government's Medical Devices Regulations; this was the only time in two years of testing that testers recall a condom did not meet the length requirement (at least 16 centimetres, or 6.3 inches). Protex was the only one tested that leaked; and one of two not to comply with the bursting volume requirement.

One lot of Ramses – two lots were tested to provide a sufficient number – had a high number of condoms that did not pass the bursting volume requirement, which put them in a borderline situation, and lab technicians say that if more were tested that lot possibly would have failed federal standards. And one Trojan condom of a group that was mechanically aged, as if bought some time ago, did not meet the bursting requirement.

The remaining brands all complied with the federal government's requirements.

Heinz Bolender, president of HYCO Products Ltd., which distributes the Protex condoms in Canada, said in a telephone interview that the samples tested may have failed because they were old or because the vending machine was located too close to the blow-dryers in the washroom.

Because The Star was seeking to simulate the random condom purchases of consumers, and researchers were asked to test only a small sample, these results do not conform to the standard Acceptable Quality Level sampling. It was simply luck of the draw, which is what consumers face.

The tests also showed that when the condoms were lubricated with Vaseline Intensive Care lotion – using an oil-based lubricant is a fairly common practice, according to experts – they *all* failed to a significant degree, according to the researchers.

At one time health officials recommended lubrication to lessen the chances of breakage, but the tests showed that, unlike water-based lubricants, oil-based lubricants such as Vaseline reduced the condoms to less than half the bursting volume allowed by the federal government.

The tests were similar to those carried out periodically by Health and Welfare Canada to ensure that condoms in Canada are reliable.

Under government regulations, every condom must:

- Have an integral rim, located at the open end of the condom in the form of a smooth, uniformly narrow, thickened ring constructed of the same material as the condom.
- Have a length of not less than 16 centimetres (6.3 inches).
- Have a width of not less than 4.5 centimetres (1.8 inches) and not more than 5.5 centimetres (2.2 inches) in the area from the rim to the measuring point (8 centimetres, or 3.1 inches, from the closed end of the condom).
- Have a width of not more than 7 centimetres (2.8 inches) in the region from the measuring point to the closed end on the condom, including the reservoir.
- Not show evidence of leakage when filled with 300 millilitres (10 fluid ounces) of water. (The regulations allow for a margin of error: It is permissible that 0.4 per cent of condoms tested in a batch fail to meet this requirement.)
- Have a bursting volume of not less than 25 litres (5.5 gallons). (It is permissible that 6.5 per cent of the condoms do not meet this requirement.)
- Have a bursting pressure of not less than 1 kilopascal. (It is permissible that 6.5 per cent of the condoms do not meet this requirement.)

The condoms are also required to pass the leakage and bursting tests after being mechanically aged, as if they had been purchased some time ago. And the condoms cannot contain or release any harmful or irritating substances.

To test for leaks, condoms are filled with 300 millilitres (10 fluid ounces) of water, dried, then rolled on a blotter. For bursting tests, they are blown up on a special machine until they burst.

As long as condom packaging is preserved, proximity to the expiry date on the package doesn't seem to weaken or deteriorate the condoms. However, the aluminum foil packaging used on Trojan-enz and LifeStyles, and the individual double packaging on Protex, probably provide better protection than the polyethylene plastic film used to package Ramses Sensitol and Beyond brands, according to researchers.

The Protex results were "the biggest failure I've ever seen here," said Rocco Melito, mechanical technologist with Retail Research Laboratories, a private lab that has tested condoms for clients, such as importers.

"I've never had any that didn't meet the minimum length, and I've never had so many bursting volume problems in the first set of 10. Since we did have so few failures in the past, I consider it a failure of that production lot," said Melito.

1 The article EM9020 *Lab tests* .... reprinted above, and the article EM9021 *Condom quality* .... which starts on the facing page 11.35, both mention .... *a small sample* .... in several places.

- Identify explicitly each sentence in the articles where this phrase (*or* the statistical issue it raises) occurs.
- Describe briefly the underlying *statistical* matter that is involved in the concern about sample size.

2 The fourth paragraph of the middle column of the article EM9020 *Lab tests* .... above states that .... *The Star was seeking to simulate the random condom purchases of consumers* ....; explain briefly the meaning of the word *random* in this context.

- Compare and contrast this meaning of *random* with that in Question 4 of Figure 11.7a (on the previous side, page 11.33).

(*continued*)

Figure 11.7b. COSTS OF POOR QUALITY AND PRODUCTIVITY: Consumer..... (continued 1)

EM9021:

Condom quality is a concern for officials

The federal government has expressed some concern about recent lab test results showing a leading brand of condoms sold in post-secondary schools performed poorly.

Because it was such a small sample – 10 to 15 of each of five brands – it's possible that only this particular lot of the Protex condoms was faulty, said Philip Neufeld, head of the standards and testing section at Health and Welfare Canada.

"It is just luck of the draw, he said in a telephone interview responding to the results of Star-commissioned laboratory tests. "The whole thing is based on statistics and probability."

However, John Riou of the federal health protection branch of Health and Welfare Canada said, "We are more than anxious to have that test data".

The federal government is concerned about the quality of *all* condoms sold in Canada as more people rely on the birth control device for protection against acquired immune deficiency syndrome, Riou said.

Officials have stepped up enforcement of federal standards and are expected to release the latest test results of every brand available on the market some time next month.

The last time the government tested, in 1987, there was a 40 per cent failure rate. At that time, Riou said, it was obvious work needed to be done to get the industry up to standards.

Meanwhile, the Canadian distributor and the U.S. supplier of Protex condoms – some of which leaked and failed the federal government's bursting and size requirements when tested by Retail Research Laboratories – say the tests performed were on too small a scale to make any conclusons about the quality of their brand.

Heinz Bolender, president of HYCO Products Ltd., which distributes the Protex condoms in Canada, said in a telephone interview that he's surprised and skeptical. The fact that the lab testers happened to get faulty condoms was "just like winning the lottery," he said.

However, Connie Clement, family planning program co-ordinato with the City of Toronto, said: "That's no justification. *Every* batch that's out there is supposed to meet government standards."

Old samples

Bolender said the samples tested may have failed because they were old and in a bad location.

"It looks like there was an oversight somewhere down the line," he said. "Possibly, someone wasn't keeping the supply up to date".

Very few condoms sell from that vending machine because it's in the women's washroom, he said.

"'You've got to think: These things have been for three years rolled up ..... once they're unrolled you can see the rippling ..... then all of a sudden they're under instant pressure. If you tested a fresh product right out of the batch you might not have any problems".

The expiry date listed on the Protex packages was Sept. 9, 1992. Two other brands were older and the testers found no quality difference among the aged condoms. Stored properly, condoms should last up to five years, experts say.

Sam Dlugatch, executive vice-president of Allercare-Nsl, which supplies HYCO with Protex, said the failures could be due to the heat in the Ryerson washroom where the condoms were purchased. Condoms should be stored in a cool, dry place.

Vending machine

After hearing the results of the test, Bolender said he investigated further and discovered the vending machine from which the tested condoms were purchased was attached to the wall between two hand-dryers. He said he will move it.

"For all the business we're doing, all the condoms that have been bought so far, all these years, there's been only one or two complaints that I've been aware of," he said.

But Sue Johansen, a sex educator and broadcaster, said she questions Protex's reliability. Johansen, whose Sunday night sex talk show on Q107 is sponsored by Julius Schmid Canada Ltd., which produces Ramses Sensitol and other condoms, said she used a few Protex from the machine at a community college as part of a demonstration on condom strength. She stretched her hand inside the condom. Usually, the condom survives, but in this case, her hand broke through. She said she purchased several more Protex and every one broke.

Ryerson Polytechnical Institute, where the tested condoms were purchased, has had the Protex machines in a men's washroom and a women's washroom since the beginning of the school year. They are there on a trial basis; the school will decide this spring whether to continue, change or expand the service. As assurance the condoms work, Ryerson stipulated in the contract with HYCO that the Protex condoms meet federal government requirements.

Top runner

"Even though the condom has been approved (by the government), we know every so often they don't meet the specs and we're really worried about that," said Viggo Jensen, director of institute services. "We're not experts down here on a thing like that."

Protex is used in vending machines on the U of T campus – some of the buildings have had machines for 20 years. Now the university is planning to expand the service.

Jim Delaney, student affairs liaison officer, said Protex was one of a very few brands available in the boxed format compatible with vending machines. He said he has heard no complaints.

Protex is one of the top runners vying for a spot in vending machines in Toronto high schools, said Jim Garrington, chief buyer for the Toronto school board.

The board is expected to decide next month which brand to approve; the successful candidate must have the blessing of the Toronto public health department and the federal government, Garrington said.

School boards

The machines are expected to be installed in April.

Garrington said he has been getting calls from school boards all over Canada that are considering installing machines and want to see Toronto's data once trustees have decided.

The federal government is in the midst of a survey of all brands available on the market. The results will be released in March, Riou said.

The condom market has heated up since the AIDS scare.

Sales are 50 per cent higher since it became publicized that condoms can help prevent the disease, said Murray Black, president of Julius Schmid Canada Ltd.

New brands have flooded the market in recent years, he said. They usually don´t last, Black said, when they collide with tough government standards.

All the brands tested for The Star are considered leading brands of condoms, manufactured by established companies.

Though there seems to be a smorgasbord of condom varieties out there, Dr. John Robertson said the number of fly-by-night importers seems to have decreased.

Robertson, of Technitrol-Eco, a contract laboratory that has tested many condoms, said: "There was a time when it was obvious condoms were going to be important and people discovered you could buy them from the Orient quite cheaply. But some of those condoms weren't very good."

1995-04-20

(*continued overleaf*)

Clement said she is most concerned about condoms made in Thailand and Korea, where there is no quality control.

Riou said the federal government keeps an "import watch": when new brands come through customs, officials ask manufacturers for information about the production to ensure the condoms are up to Canadian standards. If that's not available, they do the analysis themselves. The federal government is also advised of U.S. tests and does periodic tests at the retail level.

Studies have shown that not all condoms work equally well and may vary with different tests.

Consumer Reports tested 40 varieties of condoms and found a projected failure rate of more than 10 per cent in some brands. However, Protex varieties ranked somewhere in the middle.

Popular brands

UCLA researchers found the AIDS virus leaked in one of 10 condoms tested in each of three popular national brands (LifeStyles Conture, Trojan Naturalube and Trojan Ribbed) and in six of 25 tested in a fourth brand (Contracept Plus). Those 25 apparently came from a batch that had deteriorated during storage. An industry spokesman said all condoms met federal requirements.

Robertson said it may be time for the Canadian government to look at condom testing more seriously, possibly checking all new brands before they come on the market.

But most experts agree the condom is much more reliable than in the past.

Ed Jackson, director of education with the AIDS Committee of Toronto, said he's impressed with Health and Welfare Canada's attempts to keep tabs on the market.

"AIDS has finally jolted them into doing the tests much more frequently and stringently. I think they're safer than they've ever been."

"No one can guarantee 100 per cent safety with condoms, but overall they're your best bet."

Some advice

Most experts said the main reason condoms break is because of misuse. They offer this advice:

- Choose latex instead of lambskin for the best protection against AIDS.
- Store condoms in a dark, cool, dry lace.
- Open packages gently; watch fingernails don't tear.
- Leave space at the end of the condom and squeeze air from the tip.
- Avoid oil-based lubricants such as Crisco, Vaseline or baby oil. Check the label to ensure a lubricant is water-based.
- Withdraw immediately after ejaculation while holding on to top of condom.

– K.Z.

3 The fourth paragraph of the middle column of the article EM9020 *Lab tests* .... reprinted on page 11.34 refers to .... *Acceptable Quality Level sampling*. Describe briefly the proper role of such sampling in quality assurance.
- Compare and contrast the justification for such sampling in the context of the article with its use by a *manufacturer* [*e.g.*, as in Question 12 on the fourth side (page 11.14) of Figure 11.3a].

4 The fifth federal government specification for condoms, given in the article EM9020 *Lab tests* .... (near the top of the right-hand column) mentions a .... *margin of error*....; outline the meaning of the phrase in this context.
- Compare and contrast this meaning with the use of the phrase with reference to a confidence interval (*e.g.*, in the fourth paragraph of Figure 8.13b: *Scientific side of opinion polls doesn't hold up*).

5 In the third paragraph of the article EM9021 *Condom quality*.... (which starts overleaf on page 11.35), Philip Neufeld is quoted as having said: *The whole thing is based on statistics and probability*; outline what Mr. Neufeld means by this statement.

6 The seventh paragraph of the article EM9021 *Condom quality*.... refers to .... *a 40 per cent failure rate (of condoms during federal government testing)*; suggest at least *two* possible interpretations of this statement.
- Which interpretation is likely to be the correct one for the statement in the article? Briefly justify your choice.

7 Assess critically Heinz Bolender's defence of the test results for the Protex condoms, given in the article EM9021 *Condom quality*....:
- in the ninth paragraph (of the first column);
- in the third paragraph of the second column.

8 Comment critically on Connie Clement's statement in the tenth paragraph of the article EM9021 *Condom quality*....: *Every batch (of Protex condoms) that's out there is supposed to meet government standards.*

9 Assess critically Sue Johansen's method of demonstrating condom strength (by stretching her hand inside a condom), as described in the ninth paragraph of the second column of the article EM9021 *Condom quality*.....

10 Describe briefly the *statistical* issue(s) involved in Viggo Jensen's statement, given on page 11.35 in the second paragraph of the third column of the article EM9021 *Condom quality*....: *Even though the condom has been approved (by the government), we know every so often they don't meet the specs and we're really worried about that.*

11 Comment critically on Connie Clement's statement .... *where there is no quality control*, made with reference to condoms manufactured in Thailand and Korea, and given above in the first paragraph of the left-hand column of *this* page 11.36 of the articlea EM9021 *Condom quality*.....