

Contamination & Recall

Assessing, Mitigating, and Transferring the Risk

Emerging Risks

Volume 2



Prepared by:
Frank Crystal Research & Analysis Team
Frank Crystal & Company
Financial Square, 32 Old slip
New York, NY 10005

Contact:
Frank Crystal Research & Analysis Team
research@fcrystal.com

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Product Contamination and Product Recall are catastrophe exposures not typically covered by traditional Product Liability insurance. Direct costs build rapidly and costs arising from brand damage, lost shelf space, and shareholder lawsuits are long-lasting. Thorough Risk Management practices are essential to minimize the exposure and the costs of a recall event. Product Contamination and Product Recall insurance can protect the bottom line by covering brand rehabilitation expenses and the direct costs of recall. This publication will be of particular benefit to Operational, Financial, and Public Relations Executives, Risk Managers, and General Counsels at firms that manufacture or distribute consumables, cosmetics, pharmaceuticals, manufactured products, and other products or product components.

Publication Overview

This publication specifically addresses the management of product contamination and recall risks, including:

1. Assessing and quantifying the risk;
2. Mitigating the risk of recall and resulting damages; and
3. Transferring the risk.

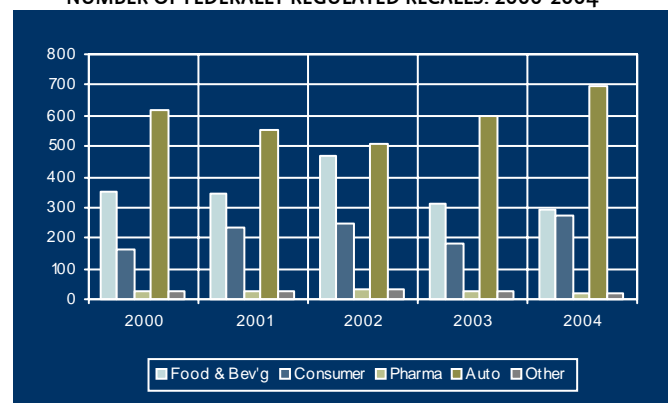
Contamination & Recall Statistics

More recalls were initiated in 2004 than in any of the previous five years. Approximately 1,375 recalls were initiated over the course of 2004 in conjunction with federal regulatory agency campaigns and activities – a total of more than 25 per week.¹ An unknown number of additional recalls were initiated voluntarily without regulatory involvement.

Recalls varied widely in scope and cost in 2004 and were initiated by both private and public firms alike. Motor vehicle parts related recalls were the most common and accounted for

just over half of the year's total. Food & beverage,² consumer products, and pharmaceutical recalls accounted for the majority of the remainder. There were also a handful of cosmetics, watercraft, and environmental related recalls.

NUMBER OF FEDERALLY REGULATED RECALLS: 2000-2004³



Some of the past twenty years' most notable recalls are outlined at the end of this publication. While the magnitude of these recalls is extraordinary, they are illustrative of the rapid pace at which recall costs mount and the catastrophic exposure many companies face. Taking steps to mitigate and transfer such risk should be a fundamental financial objective for all manufacturing companies.

The cost of executing a recall has increased astride a trend toward lean production systems, which limit inventory and decrease the time from production to consumer. Companies that have adopted lean production systems are less likely to catch a defect before a product has been distributed. Moreover, limited inventory may lead to difficulty replacing a recalled product in a timely manner.

Assessing and Quantifying the Risk

Accurately assessing exposure to recall requires projecting annualized recall costs. Such projections enhance exposure mitigation decisions and allow for a quantitative cost-benefit analysis of potential insurance solutions.

Our cost projection methodology includes two qualitative factors – a Probability Factor and a Severity Factor – to adjust for each company’s unique exposures and risk management efficiencies. This methodology is applied in a case study presented on Page 5.

Step 1: Determine the Probability Factor

The Probability Factor is a subjectively chosen number from 0 to 2 that reflects a company’s exposure relative to its peers.

Probability Factor	Relative Exposure
0.0	No Exposure
0.5	Relatively Low Exposure
1.0	Industry Average Exposure
1.5	Relatively High Exposure
2.0	Highest Exposure in Industry

The following factors should be considered:

- Those with wide international distribution patterns will face less stringent regulatory oversight that those operating primarily in U.S. and European jurisdictions.
- The more ingredients used, the greater the exposure to contamination; likewise, the more components used, the greater the exposure to malfunction.
- Those with a larger number of unique products typically face a wider and greater exposure than those with limited offerings.

Step 2: Calculate the Number of Expected Recalls Per Year

Multiply the company’s market share by the number of industry recalls per year:

$$\text{Market Share} \times \text{Annual Industry Recalls} = \text{Annual Market Share Recalls}$$

Multiply Annual Market Share Recalls by the Probability Factor to adjust for the company’s relative exposure:

$$\text{Annual Market Share Recalls} \times \text{Probability Factor} = \text{Annual Expected Recalls}$$

Step 3: Estimate the Average Batch Recall Execution Cost

How much would it cost to recall a single batch, assuming adequate inventory? The following actions must be considered:

- Communications to Announce a Recall
- Transportation and Other Costs to Withdraw a Product from Market
- Product Testing and Temporary Storage
- Product Disposal
- Overtime Wages and Extra Help Salaries
- Brand Rehabilitation
- Lost Revenue
- Public Relations Campaign
- Crisis Response Consultancy Fees
- Product Redistribution and Replacement
- Shelf Slotting and Advertising Cancellation Fees

Step 4: Estimate the Average Number of Batches Recalled

Based on production cycle length and shelf-life, how many units would likely be recalled? Determine the number of batches accordingly.

Step 5: Determine the Severity Factor

The Severity Factor is a subjectively chosen number between 1 and 5 that reflects inventory size.

Severity Factor	Inventory Size
1.0	Very Large ↑ ↓ Very Small
2.0	
3.0	
4.0	
5.0	

A large inventory will allow rapid replacement of a recalled product whereas a small inventory may inhibit replacement and protract the recall period. Severity Factors of 2.5 to 3.5 are typically appropriate for lean production systems.

Step 6: Calculate the Projected Annual Recall Cost

Multiply Expected Recalls Per Year (Step 2) by the estimated Batch Recall Cost (Step 3) and Number of Batches (Step 4):

$$\text{Annual Expected Recalls} \times \text{Batch Recall Cost} \times \text{Batches} = \text{Annual Base Cost}$$

Multiply the resulting Projected Annual Base Cost by the Severity Factor (Step 5):

$$\text{Annual Base Cost} \times \text{Severity Factor} = \text{Projected Annual Recall Cost}$$

Of note, the Projected Annual Recall Cost accounts for the costs incurred in the more common, isolated recall incidents. Exposure to a catastrophic recall, in which a large portion of a product line is recalled, must be considered in addition.

Assessing Contractually Transferred Risk & Indirect Costs

Brand owners that contract portions of the production cycle should not depend solely on the contractual transfer of recall costs. The contracted company may not be capable of meeting its financial obligations or it may be difficult to prove whose product is ultimately at fault. As such, the brand owner should explore the option of transferring its own risk through insurance or of requiring that its contractors transfer their own risks to financially stable insurers. Because brand reputation is more valuable than the services provided by contractors, recall risk should always be managed by the brand owner.

Publicly held companies must be concerned with investor confidence. A recall will often lead to a drop in stock price and shareholder lawsuits against the management. When structuring the corporate Directors & Officers Liability insurance program, the potential for such a situation should be considered and appropriate terms negotiated. Risk Management and Loss Control costs are likely to increase following a recall as systems are modified and new procedures implemented. Payment for, or loss of, shelf and retail inventory space will also be necessary, particularly if product consumption decreases substantially. All such costs should be factored into any recall analysis and crisis response contingency plan.

Mitigating the Exposure and Potential Damages

Carefully planned and continuously executed mitigation strategies are essential to the long-term financial well-being of a company and proactive measures should be implemented to:

- Mitigate the exposure to recall; and
- Mitigate potential damages.

Food and beverage, cosmetics, and pharmaceutical companies must take special terrorism precautions in addition to following standard loss control procedures.

Mitigating the Exposure to Recall

Many manufacturers employ a total quality management (TQM) approach to production. The maintenance of Hazardous Activities Critical Control Points (HACCP) sheets monitoring product flow in key areas, such as mixing, makeup and metal detecting, is now considered a necessity by many corporate and industry standards. Risk Managers that have HACCP sheets in place must enforce adherence to the plan. Most contaminations and tamperings occur only when HACCP plans are not followed.

Thorough risk management and loss control systems can mitigate the risk of contamination or the development of a defective product. Food & Beverage companies should:

- Monitor Facility & Staff Cleanliness
- Sample Test Ingredients
- Sample Test Product
- Meet and Exceed all Child- and Tamper-Resistant Packaging Requirements

Manufacturers should:

- Sample Test Raw Materials
- Sample Test Third-Party Components
- Optimize Batch Size
- Clearly Identify Each Individual Product

Managing the Terrorism Risk

Food and beverage companies that have large central stores of product, that use ingredients originating from large central stores, or that have a single product with wide distribution all face the potential that their products may be targeted as mechanisms for terrorism. Large central stores must be monitored closely and each batch sample-tested throughout the processing cycle. Transportation methods should also be monitored carefully. Companies that purchase ingredients that originate from large central stores should carefully inspect and sample-test each received batch. Enhanced TQM and HACCP plans should also be adopted.

Mitigating Potential Damages

Every company with a recall exposure should have a clearly defined response strategy in place and have a designated team

coordinated to manage a product recall crisis. Such a team should include the:

- Risk Manager
- General Counsel
- Chief Executive Officer / Chief Operating Officer
- Public Relations Executive
- Marketing Executive
- Quality Control and Safety Executives
- Engineering Managers
- Production Managers
- Distribution Managers

In addition, the team should include an outside attorney, a public relations firm, and an insurance brokerage Claims Management team, all with recall and relevant business industry experience.

Production should be halted at the first suspicion of non-compliance with standards or a safety defect and it should be immediately determined if:

- There is a defect or contamination of components, or ingredients supplied by others
- The product can be isolated by line, by shift, or by plant
- The contamination occurred in the raw ingredients or during manufacturing, packaging, warehousing, or shipping
- There is danger of further contamination
- The defective/contaminated product is still within the company's or its retail distributors' control

Depending upon the results of these questions, the recall response team must determine whether or not to initiate a recall. If a recall is initiated, all corporate staff and the proper government agency should be notified first, followed by users, and lastly the public via a press release. When notifying the corporate staff, specific directions should be given to effected departments, such as the Accounting department, which will need to record all costs associated with the recall.

Managing a Recall Claim

When a recall is initiated and a Product Contamination or Product Recall policy is in place, the underwriter must be notified immediately. Accurate, detailed expense records must be kept in order to obtain timely indemnification and to maintain cash flow to the bottom line. The broker's Claims Management team must be able to guide the company in making the proper decisions so as to comply with the conditions of the insurance policy. The broker's Claims Management team must also be able to serve as the company's advocate in the event any insurance related issues arise.

Transferring the Risk

In many cases, recall risk can be effectively transferred through insurance. Product Contamination insurance policies provide coverage for food and beverage, cosmetics, and pharmaceutical companies. Product Recall insurance policies provide coverage for parts and other consumer products. Policy Contamination and Policy Recall insurance differ significantly in the coverage provided and availability.

Policy Trigger

Product Contamination policies respond *upon discovery of an actual or alleged, accidental or malicious contamination*. For example, the standard language of one major Product Contamination insurer reads:

Underwriters agree to indemnify the Named Insured for LOSS resulting directly from a PRODUCT TAMPERING . . . [or an] ACCIDENTAL PRODUCT CONTAMINATION first discovered by the Named Insured during the Certificate Period.⁴

In contrast, Product Recall policies respond *in conjunction with a recall initiated as a result actual or imminent danger of bodily injury or property damage caused by a given product*. One major Product Recall insurer's standard policy reads:

This insurance applies to compensatory damages caused by . . . the recall, removal, recovery of possession or control, or disposal of Your Product(s) . . . because the use or consumption of Your Product(s) has resulted in bodily injury or property damage, or poses actual and imminent danger of resulting in "bodily injury" or "property damage".⁵

The date of the actual production, contamination, or tampering of a product is not relevant when determining the responsiveness of a Product Contamination or Product recall policy. Note that these coverage triggers are event-oriented and most policies will provide coverage regardless of whether a recall is voluntary or federally mandated.

Coverage Sections: Product Contamination Insurance

Product Contamination policies provide two sections of coverage that may be secured either independently or with shared limits:

- Accidental Contamination – Coverage for fault in design specification, unintentional contamination during pre-distribution phases, or mislabeling that may result in bodily injury
- Malicious Contamination – Coverage for actual or threatened intentional malicious alteration or contamination, including for terrorist purposes

The scope of accidental contamination coverage tends to vary. Some policies only provide coverage if the contamination was caused by an external substance. Such a condition will result in a significant coverage gap in certain situations.

Covered Costs

Both Product Contamination and Product Recall policies generally cover costs associated with:

- Communications Announcing a Recall
- Transportation and Other Costs to Withdraw a Product from Market
- Product Testing and Temporary Storage
- Product Disposal
- Overtime Wages and Extra Help Salaries

Many Product Contamination policies also cover:

- Brand Rehabilitation
- Lost Revenue
- Public Relations Campaign
- Crisis Response Consultancy Fees
- Product Redistribution and Replacement
- Shelf Slotting and Advertising Cancellation Fees

When exploring the cost benefit of securing Product Contamination or Product Recall insurance, the coverage options provided by different policies should be carefully compared. The suitability of each policy varies by risk.

The scope of malicious contamination coverage also tends to vary, though most policies provide coverage for terrorist related contamination.

Some Product Contamination policies also provide coverage for Extortion. However, such coverage is typically limited. In most cases, comprehensive extortion coverage may be obtained through a separate Kidnap, Ransom, & Extortion ("KR&E") insurance policy. It is possible to secure only the Extortion coverage section of a KR&E policy, if desired.

While extortion attempts have been relatively rare in the United States, they are not uncommon in other regions. In November 1998, Nestle recalled its products in 44 Grosse supermarkets in Germany due to an extortion demand and the finding of poisoned products throughout the country. More recently, in May 2005, a man in Taiwan poisoned several bottles of Bullwild and Paolyta B drinks with cyanide. While he intended to submit an extortion letter to the producer, the death of an individual led to his arrest before the letter was sent.

Product Contamination insurance policies generally provide first-party coverage, but many also provide third-party coverage. Companies that do not ship direct to market should evaluate the benefit of third-party coverage.

Of note, both Product Contamination and KR&E insurance policies require that the insured use all reasonable efforts not to disclose the existence of the policy, unless required to do so by law. The disclosure of such insurance may instigate an extortion attempt.

Coverage Sections: Product Recall Insurance

Product Recall policies are also typically divided into two coverage sections that may be purchased independently or combined:

- Coverage for First-Party claims, covering the recall costs incurred by the insured
- Coverage for Third-Party claims, covering the recall costs incurred by a company reselling the insured’s product or using the insured’s product as a component part

Product Recall policies tend to be secured with high retention levels and the policy language is manuscripted to the exposure and the limits required.

In many cases Product Recall insurance is prohibitively expensive, particularly for companies attempting to secure both coverage sections. The high cost of Product Recall insurance is a result of the limited extent to which the risk may be spread due to the nature of the consumer product marketplace and the limited number of insurers willing to underwrite the risk.

Other Applicable Insurance Coverages

To comprehensively transfer the financial risks associated with a product recall, an insurance program should be structured with either Product Contamination or Product Recall insurance and the following coverages. However, every exposure is unique and warrants individual attention to determine the cost benefit of obtaining insurance coverage.

Directors & Officers Liability Insurance

Covers claims against directors and officers; Such claims are common after stock prices drop, which often occurs in response to a recall.

Kidnap, Ransom & Extortion Insurance

The Extortion coverage section provides comprehensive coverage for the extortion monies and extortion-related costs that may be incurred if a product is contaminated or threatened to be contaminated for extortion purposes. While a Product Contamination policy will cover the recall costs associated with an extortion demand, most will not comprehensively cover the extortion related costs and events.

Products Liability Insurance

Covers claims arising out of bodily injury or property damage; Specifically excludes coverage for recall expenses.

Case Study

One of Frank Crystal & Company’s clients, a food production company with \$300 million in annual revenue, has a product contamination exposure: Our assessment of this exposure is as follows:

Market Share:	0.06%	\$300,000,000 Company Revenue / \$500,000,000,000 Industry
Industry Recalls:	354	Average Number of Food & Beverage Recalls Over Last 5 Years
Probability Factor:	0.6	Exclusive U.S. Distribution; Very Few Ingredients; Limited Number of Products
Estimated Batch Recall Cost:	\$150,000	Provided by Client (Assuming Inventory Adequate to Meet Instant Needs)
Estimated Number of Batches	5	Provided by Client (Batch Size is Average)
Severity Factor:	1.6	Inventory Somewhat Limited Due to Perishable Stock
Projected Annual Recall Cost:	\$152,928	Market Share • Industry Recalls • Probability Factor • Batch Cost • Severity Factor

Frank Crystal & Company negotiated a Product Contamination policy with a \$10,000,000 limit for this firm for an annual premium of \$165,000. This premium is slightly higher than the Projected Annual Recall Cost, but the \$10,000,000 limit is substantially greater than the losses expected, providing a very large cost benefit in the event of a catastrophe recall.

Prior to this year, the client had not initiated a recall during out tenure servicing the firm (approximately five years). However, this year the client was in a situation in which a recall was necessitated. While the terms of the recall fell within a gray area, not specifically outlined in the policy language, we were able to advocate on behalf of the client and the insurer has agreed to pay full indemnification for the loss, which is estimated at almost \$3,000,000, excluding lost revenue.

¹ Information from the Consumer Product Safety Commission, United States Department of Transportation, United States Coast Guard, United Food & Drug Administration, United States Department of Agriculture, and the United States Environmental Protection Agency. All data consolidated and compiled by Frank Crystal & Company. Data set does not include Category 3 recalls, which do not pose a threat of Bodily Injury.

² Includes recalls of meat and poultry. Does not include Category 3 recalls, which do not pose a threat of Bodily Injury.

³ See Footnote 1.

⁴ Professional Indemnity Agency, Inc. *Specimen Form MPT-APC (Ed. 2-01)*.

⁵ MaxRe. *Specimen Product Recall Policy*.

Significant Product Contamination and Product Recall Events

Brand	Year	Problem	Bodily Injury	Recall Volume	Recall Cost	Event Implications
Tylenol	1982	Capsules laced with cyanide (after shipment)	7 Deaths	31,000,000 bottles	\$100,000,000+	Brand made successful recovery, often attributed to public relations strategies including first Brand to meet new tamper-resistant bottling standards
Perrier	1990	Excessive levels of Benzene found in bottles in both US and Europe	No Injuries	230,000,000 bottles (entire worldwide inventory)	\$200,000,000	As of 2000, revenue still 40% below that earned in 1989
Pepsi	1993	Needles and other objects discovered in cans of Diet Pepsi, determined to be a hoax fueled by media reports and copycat	No Injuries 53 arrests Several convictions	Recall not issued	\$35,000,000 in lost revenue, marketing, and increased coupon costs	Substantial brand rehabilitation including worldwide video news package and full page advertisements
Jack in the Box	1993	E. coli outbreak traced to meat from 73 Jack in the Box restaurants in Washington, Idaho, California, and Nevada	700 people fell ill, 4 child deaths	All hamburger meat recalled from Jack in the Box restaurants	\$160,000,000 in incurred costs and reduced sales	Rehabilitated brand by developing and implementing a production-to-consumption HACCP-based food safety system that is considered the gold standard for food-service
Coca-Cola	1999	Although never confirmed, sulfur compounds may have been present in some products and odors present on some cans in Belgium and France, some academics believe the only issue was mass hysteria	100 children felt ill	Total recall in Belgium, limited recall in six other countries.	\$100,000,000	Belgium banned sale of all Coca-Cola products for a limited time, all Belgians given free product upon market reentry
Firestone	2000	A fault in some tires lead to relative risk of tread separation	Numerous deaths and injuries attributed to tread separation and resulting motor vehicle rollover	7,260,000 tires	\$1,800,000,000 reserved or paid for recall and product liability costs	Unit sales of the Firestone brand remain below peak level
Dasani	2004	Excessive levels of Bromate formed in water after addition of Calcium Chloride to meet UK Calcium requirements	No injuries	500,000 bottles	\$32,000,000 in incurred expenses	Dasani brand has struggled in Europe
Sudan 1	2005	Chili powder colored with illegal red dye inadvertently used in batch of Worcester sauce, used in numerous other products	No Injuries	580 products from approximately 300 producers	\$360,000,000	Brand damage spread among numerous companies

Data compiled from various SEC filings, publicly available annual reports, and various news sources.