MINI PAPER

A TUTORIAL ON PROBABILISTIC RISK ASSESSMENT FOR NET PACKAGE CONTENTS

Dennis W. King, PhD, Consulting Statistician
STATKING Consulting Inc., 780 Nilles Road, Fairfield, OH 45014

Introduction

In both the US and foreign countries, government regulations are in place to monitor the contents of packaged products. Inspectors from regulatory agencies routinely sample packaged products from store shelves and measure the contents of the sampled packages to guarantee that the consumer receives the amount of product indicated by the product label.

In most package filling processes, packages are filled by some sort of filling mechanism which dispenses product into the bag or container. These filling mechanisms fill packages to a specified fill level sometimes called the target fill level. Each package to be filled is subject to the inherent variability of the filling mechanism or process which causes the actual package fill levels to be dispersed around the target fill level.

The dilemma faced by the producer is where to set the target fill level for the filling process. The producer wishes a fill level which will minimize the overfilling of packages and the risk of filling packages below their labeled content value.

An interesting application of probabilistic modeling concerns the computation of the risk of the producer being in violation of package contents regulations based on a sample of product taken from store shelves. It is the purpose of this paper to discuss some basic examples in the calculation of probabilistic risk assessment of violations of package fill regulations. Since many sets of regulations exist, no one set will be singled out but rather two of the most general sorts of regulations will be discussed.

Statistical Considerations

For all of the discussion in this paper, it will be assumed that the distribution of actual package fill levels follow the normal distribution (bell shaped curve) and that package fill levels are independent over time. It is also assumed that the target fill level of the filling process is not subject to error or drift, i.e., once the target fill level is set on the filling mechanism this level represents the center of the fill level distribution until such time that the target fill level is reset. Any of the examples discussed below could be modified to compute risk for non-normally distributed or serially correlated package fill levels but the statistical theory becomes more complex and the ability to compute the risk probabilities requires more sophisticated statistical software.

Case I. Regulations Based on Mean Contents

Suppose that the regulatory agency policy is to require that the average fill level of a sample of ten cans cannot be less that the labeled fill level (LFL) of the package. Denoting the sample mean as $\overline{X}_{10}$, the risk of being in violation of the regulatory agency guideline is the probability that the sample mean of ten packages is less than the LFL. In statistical notation, this is $P(\overline{X}_{10} < LFL)$. Note that this probability is a function of the mean of the distribution of the package contents. The mean of this distribution is given by the setting of the filling mechanism, i.e., the target fill level.

It can be shown through probabilistic arguments that

$$P(\overline{X}_{10} < LFL) = P(Z < \frac{LFL - \mu}{\sigma / \sqrt{n}})$$

where Z has a standard normal distribution, μ is the target fill level and σ is the process standard deviation. This last probability can be read from widely available tables of the standard normal distribution or can be computed using the standard normal probability function that is available on many hand calculators.

Example

Let's look at an example using the above probability calculations. Suppose the labeled weight of a package of granular garden fertilizer is 64 ounces. The filling mechanism is set to fill packages at 64.05 ounces. From historical data on the filling mechanism, the distribution of fill weights around the target fill level has a standard deviation of .3 ounces. For a sample of size n=10,

$$P(\overline{X}_{10} < LFL) = P(Z < \frac{64 - 64.05}{.3 / \sqrt{10}}) = P(Z < -.52705) = .29908,$$

i.e., there is about a 30% chance of being in violation of the regulatory agency policy at a filler setting of 64.05 ounces. A projection of the risk for different settings of the filler mechanism is shown in Table 1.

In this case, there is approximately a 30% chance that the average of ten packages will be below the LFL if the target fill level is 64.05 ounces. If the target fill level is set at 64.16 ounces, there will be less than a 5% chance that the average of ten randomly sampled packages is below the LFL. The risk of being in violation decreases as the target fill level increases. It is the job of management to reach

a compromise between the level of risk of being in violation and the amount of package overfill to be tolerated.

**Table 1. Risk of Being in Violation for Various Filling Mechanism Settings
Under the Case I Regulation**

Target Fill Level (in ounces)	Risk of Violation
64.05	.29908
64.06	.26354
64.07	.23030
64.08	.19954
64.09	.17139
64.10	.14592
64.11	.12313
64.12	.10295
64.13	.08529
64.14	.07001
64.15	.05692
64.16	.04585

Case II. Regulations Based on Individual Package Contents

Another type of regulatory requirement is to place a restriction on the fill levels of individual packages sampled from store shelves. Suppose that a regulatory agency requires that all the packages in a sample of size n must exceed a specified cutoff level, say, for example, 99% of the LFL.

If a random sample of size n is collected from the store shelves, the risk of being in violation of this type of regulation is

$$1 - P(\text{all } X_i > .99 \times LFL) = 1 - [1 - P(Z < (.99 \times LFL - \mu)/\sigma]^n$$

where Z has a standard normal distribution, μ is the target fill level and σ is the process standard deviation. This probability can be computed with the help of the standard normal probability function which is available on many hand calculators.

Example

Returning to our example concerning packages of garden fertilizer, with a labeled fill weight of 64 ounces and a standard deviation of .3 ounces, the risk that any of the fill levels in a sample of size n=10 from store shelves are less than the labeled fill weight is

$$1 - [1 - P(Z < \frac{.99 \times 64 - 64.05}{.3})]^{10} = 1 - [1 - .01072]^{10} = .10221,$$

i.e., the risk of being in violation of the regulatory agency policy at this filler setting is .10221. A projection of the risk for different settings of the filler mechanism is shown in Table 2.

**Table 2. Risk of Being in Violation for Various Filling Mechanism Settings
Under the Case II Regulation**

Target Fill Level (in ounces)	Risk of Violation
64.01	.14140
64.02	.13065
64.03	.12055
64.04	.11108
64.05	.10221
64.06	.09393
64.07	.08621
64.08	.07902
64.09	.07233
64.10	.06613
64.11	.06039
64.12	.05508
64.13	.05017
64.14	.04565

By comparing Tables 1 and 2, it can be seen that the regulation described in Case II provides a smaller risk to the producer of being violation for a particular target fill level. This will allow the company to operate at a lower target fill level while maintaining the "same" level of risk as the Case I regulation. The Case II regulation requires a target fill level of 64.14 ounces to produce a less than 5% chance of being in violation while the Case I regulation requires a target fill level of 64.16 ounces to produce the "same" level of risk.

An Extension to Case II

An extension of the Case II regulation described above is to allow no more than k of the n sampled packages to be below a specified cutoff value (99% of LFL in the case of our example). This type of regulation recognizes the fact that a few spurious fill levels can occur from time to time in the process and does not penalize the producer for these outliers.

In order to compute the risk for this generalization of the Case II regulation, it is necessary to compute the probability that k+1 or more packages in a sample of size n are below the LFL. From well known results for the binomial distribution given in statistics texts such as Snedecor and Cochran (1980), the general formula for this risk is

$$1 - \sum_{i=0}^{k} \binom{n}{i} \cdot p^i \cdot (1-p)^{n-i}$$

where p is the probability that an individual package is below the LFL. This probability is given by

$$p = P(X_i < .99 \times LFL) = P(Z < \frac{.99 \times LFL - \mu}{\sigma})$$

where Z has a standard normal distribution, μ is the target fill weight and σ is the process standard deviation. Both the above probabilities can be computed using a hand calculator or packaged statistical software.

Example

To illustrate the more general type of regulation, assume now that for packages of bird seed the regulation states that there is no violation if no more than one package in a sample of size n=20 is below 99% of the LFL. The LFL is 64 ounces. For a target fill level of 64.05 ounces and a process standard deviation of .4 ounces, the risk is given by

$$1 - \sum_{i=0}^{1} \binom{20}{i} \cdot (.042264)^i \cdot (1 - .042264)^{20-i} = .20627$$

since

$$p = P(X_i < .99 \times LFL) = P(Z < (.99 \times 64 - 64.05)/.4) = .042264$$

i.e., the risk of being in violation of this regulatory requirement at the target fill level of 64.05 ounces is .20627. A comparison of the risk projections for different settings of the filler mechanism and different values of k is shown in Table 3.

In Table 3, it can be seen that as the regulation is relaxed (i.e., the allowable number of packages below 99% of LFL is increased), the risk to the producer becomes smaller and the target fill weight required to produce a prespecified risk to the producer is lowered. For instance, if k=0 packages are allowed to be below 99% of the LFL, the target fill level must be 64.50 ounces to produce a less than 5% chance of being in violation. If the regulation

requires that one or less packages be below 99% of LFL, the target fill level must be 64.20 ounces. If the regulation requires that two or less packages be below 99% of the LFL, the target fill level must be 64.10 ounces to produce a less than 5% chance of being in violation.

Table 3. Risk of Being in Violation for Various Filling Mechanism Settings Under the Extended Case II Regulation

Target Fill Level (in ounces)	Risk of Violation k=0	Risk of Violation k=1	Risk of Violation k=2
64.05	.57838	.20627	.05028
64.10	.47988	.13426	.02517
64.15	.38652	.08308	.01178
64.20	.30269	.04901	.00518
64.25	.23090	.02765	.00214
64.30	.17190	.01496	.00084
64.35	.12513	.00779	.00031
64.40	.08921	.00390	.00011
64.45	.06237	.00189	.00004
64.50	.04282	.00088	.00001
64.55	.02889	.00040	<.00001
64.60	.01918	.00018	<.00001

Conclusions

This paper has looked at some of the basics of risk calculations relating to some general package fill regulations. It has been shown that the basic calculations can be carried out on calculators with the ability to compute probabilities using the standard normal and the binomial cumulative distribution functions. For an example of regulations concerning net contents of packaged goods, see Brickenkamp et al (1981) and the accompanying review article published by Lauer (1982).

References
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