# Application of the Bayesian conformity assessment framework from JCGM 106:2012 for lot inspection on the basis of single items

Steffen Uhlig¹, Bertrand Colson¹, Rainer Göb², Petra Gowik³

<sup>&</sup>lt;sup>1</sup> QuoData GmbH

 $<sup>^2</sup>$  Julius-Maximilians-Universität Würzburg, Institut für Mathematik, Angewandte Stochastik

 $<sup>^3</sup>$  BVL

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#### 1 Introduction

## 1 Introduction

In this paper we consider a special type of lot inspection, which can be briefly described as follows.

#### Aspect 1

Due to external constraints, acceptance/rejection is based on the test result from a single item taken from the lot.

#### Aspect 2

The measurand X is distributed as follows:

- for many items, we have X=0
- for some proportion of items p, X follows a distribution which, in general, is not normal.

These two aspects clearly make it impossible to apply ISO 3951 [1] (inspection by variables) or ISO 2859 [2] (inspection by attributes).

This scenario is no theoretical construct; on the contrary, it represents a real-life situation (e.g. testing for veterinary drug residues in imported products of animal origin, where p represents the proportion of animals having been treated for a disease). While this scenario clearly falls under the broad category of lot inspection, the focus is quite different from that of the above-mentioned ISO standards. Indeed, since the sample size is known in advance (determined as it is by external constraints), the main question is not determining sampling size, but rather determining consumer risk (CR) and producer risk (PR).

In this scenario, the decision regarding lot conformity is made on the basis of a single item. For this reason, it is necessary to involve prior information, i.e. a Bayesian approach is required. Such an approach is described in JCGM 106 [3] in connection with the conformity assessment of an individual item rather than a lot. Background information regarding the role of Bayesian statistics in conformity assessment and in connection with measurement uncertainty can be found in [4], [5], [6] and [7].

The following questions will be discussed:

- 1. Can JCGM 106 [3] be applied not only in connection with the conformity of a single item, but also in connection with lot inspection?
- 2. Even though the above situation fits neither in ISO 3951 nor in ISO 2859, it is possible to establish a common (more general) framework?
- 3. Which conclusions can be drawn regarding CR and PR?

## 2 Description of the situation using the notation from JCGM 106

## 2 Description of the situation using the notation from JCGM 106

In JCGM 106, Y characterizes an individual item (see, for instance, §4 in the Introduction to JCGM 106 [3]). Here, on the other hand, we consider Y to characterize a lot (e.g. Y consists of summary statistics). This extension does not affect the validity of any of the procedures or formulas in JCGM 106 [3]; nor is it incompatible with the framework of conformity assessment, which covers not only items, but also processes etc. (See, for instance §1 in the Introduction to JCGM 106 [3].)

This extension means that the specific and global risks discussed in Section 9 of JCGM 106 can be re-interpreted in the context of lot inspection.

We begin by defining a vector-valued random variable Y (whose role corresponds to the measurand in [3]) with realizations

$$y = (p, \mu, \sigma)$$

with

$$\begin{cases} X \sim \mathcal{N}\left(\mu, \sigma^2\right) & \text{for } Z = 1 \\ X = 0 & \text{for } Z = 0 \end{cases}$$

and

$$Z \sim \text{Bernoulli}(p)$$

Note: for the sake of simplicity, X is assumed to be normally distributed, but this will not typically be the case. If the test results follow a lognormal distribution, then a normally-distributed X can be thought of as the log-transformed values of the nonzero test results.

The prior distribution of Y, denoted  $g_0(y)$ , thus consists of information regarding both the proportion p of items in the lot with X > 0 and the distribution of the X > 0 values. More specifically, p is modeled as a beta distribution with hyperparameters  $\alpha_0$  and  $\beta_0$ . A given lot's mean value  $\mu$  (for the X > 0 values) is itself modeled as a normal distribution  $\mathcal{N}\left(\mu_0, \theta_0^2\right)$ . A given lot's dispersion  $\sigma$  (for the X > 0 values) could be modeled in terms of a chi-squared distribution, but as this parameter will play no role in the following, we will not dwell on this aspect here.

In summary:

$$p \sim \text{Beta}(\alpha_0, \beta_0)$$
  
 $\mu \sim \mathcal{N}(\mu_0, \theta_0^2)$ 

The prior distributions can be considered to characterize the underlying the process giving rise to the individual lots. For instance, the proportion of items with X > 0 may differ from lot to lot, and the prior distribution for p codifies prior information regarding the distribution of p across different lots.

Let U denote the upper specification limit (for X) and let QL denote some relevant Quality Level (e.g. AQL or LQ, or some intermediate quality level) in relation to which the set of conforming values is specified. Just as in the ISO standards for acceptance sampling

## 2 Description of the situation using the notation from JCGM 106

mentioned above, the QL is expressed in terms of the percentage of nonconforming items in the lot.

Following the notation from JCGM 106, the set of conforming values for Y is thus

$$C = \{y = (p, \mu, \sigma); P(X > U | y) \le QL\}$$

When a given lot is inspected, a single item is taken and a measurement is performed. The test result  $x_m$  corresponds to the realization of the random variable  $X_m$ .

Similarly to the measurand Y, we introduce the following notation for the random variables governing the measurement process leading to a test result  $x_m$  for a given lot:

$$\begin{cases} X_m \sim \mathcal{N}(\mu, \sigma^2) & \text{for } Z_m = 1 \\ X_m = 0 & \text{for } Z_m = 0 \end{cases}$$

and

$$Z_m \sim \text{Bernoulli}(p)$$

The likelihood function corresponding to a measurement  $x_m$  is denoted  $h(x_m|y)$ . (Recall that  $y = (p, \mu, \sigma)$  codifies available information regarding both p and the distribution of X.)

The posterior distribution for Y is denoted  $g(y|x_m)$ .

The acceptance interval for  $X_m$  is

$$\mathcal{A} = \{x_m; x_m \le A\}$$

where A denotes the acceptance limit. For instance, A may take the form  $U+2\cdot\sigma$ , see Section 8.3.3 (guarded rejection) in [3].

Following sections 7.1 and 9.3.2 in [3], given a test result  $x_m \in \mathcal{A}$ , the specific consumer risk is

$$R_C^* = \int_{\overline{C}} g(y|x_m) \, \mathrm{d}y. \tag{1}$$

Similarly, given a test result  $x_m \in \overline{\mathcal{A}}$ , the specific producer risk is

$$R_P^* = \int_{\mathcal{C}} g(y|x_m) \, \mathrm{d}y. \tag{2}$$

Following Section 9.5 in [3], the global consumer risk is

$$R_C = \int_{\overline{C}} \int_A g_0(y) h(x_m|y) \, \mathrm{d}x_m \, \mathrm{d}y. \tag{3}$$

Similarly, the global producer risk is

$$R_P = \int_{\mathcal{C}} \int_{\overline{\mathcal{A}}} g_0(y) h(x_m|y) \, dx_m \, dy.$$
 (4)

## 3 Procedure for lot inspection on the basis of prior information

It should be noted that the global consumer and producer risks are driven by the prior distributions, and may not always provide valuable information.

The following distinction should also be borne in mind: in the specific consumer and producer risks, the starting point is acceptance or rejection based on a test result  $x_m$ , and the question is the probability that the lot is actually compliant. By contrast, in the acceptance sampling ISO standards mentioned above, the starting point is the quality level, and the question is the probability of acceptance.

Thus, in ISO 3951-2 [1], the producer risk is defined as the "probability of non-acceptance when the quality level has a value stated by the plan as acceptable." Typically the quality level at which the producer risk is evaluated is AQL. Likewise, in [1], the consumer risk is the probability of acceptance when the quality level is not acceptable. (Note that in [1], the consumer risk is 10 %.) The definitions of CR and PR in JCGM 106 and in the ISO acceptance sampling standards thus go "in opposite directions."

Producer risk:

JCGM 106 Specific producer risk:  $P(Y \in C | x_m \in \overline{A})$ ISO acceptance sampling Producer risk:  $P(x_m \in \overline{A} | Y = y \in C)$ 

Consumer risk:

JCGM 106 Specific consumer risk:  $P\left(Y \in \overline{C} \mid x_m \in A\right)$ ISO acceptance sampling Consumer risk:  $P\left(x_m \in A \mid Y = y \in \overline{C}\right)$ 

These "opposite directions" illustrate the antithesis between Bayesian and Frequentist inference.

## 3 Procedure for lot inspection on the basis of prior information

It is assumed that, based on previous inspections, hyperparameters for the prior distribution of Y have been determined.

When a new lot is inspected, and the test result  $x_m$  has been obtained, the parameters for the posterior distribution are calculated as follows.

For p, the posterior is a beta distribution with hyperparameters

$$\alpha_1 = \alpha_0 + z_m$$
$$\beta_1 = 1 + \beta_0 - z_m$$

where  $z_m$  is the corresponding realization of  $Z_m$ , i.e.

$$z_m = \begin{cases} 1 & \text{for } x_m > 0 \\ 0 & \text{for } x_m = 0 \end{cases}$$

## 3 Procedure for lot inspection on the basis of prior information

For  $\mu$ , the posterior is a normal distribution with hyperparameters

$$\theta_1^2 = \left(\frac{1}{\theta_0^2} + \frac{1}{\sigma^2}\right)^{-1}$$
$$\mu_1 = \theta_1^2 \cdot \left(\frac{\mu_0}{\theta_0^2} + \frac{x_m}{\sigma^2}\right)$$

In summary, for the posterior distribution, we have:

$$p \sim \text{Beta}(\alpha_1, \beta_1)$$
  
 $\mu \sim \mathcal{N}(\mu_1, \theta_1^2)$   
 $\sigma = \sigma$ 

We will now take a closer look at the specific consumer risk and the evaluation of the expression for  $R_C^*$  in Equation (1).

In the following, we will use the following notation:

 $B(\cdot,\cdot)$  denotes the beta function

 $f_{\mu,\sigma}$  denotes the PDF of the normal distribution

 $z_q$  denotes the q quantile of the standard normal distribution for  $q \in (0,1)$ .

We first note that  $p \leq \mathrm{QL} \implies y = (p, \mu, \sigma) \in \mathcal{C}$ . Accordingly, for the evaluation of the integral for  $R_C^*$ , we need to integrate over the range  $\mathrm{QL} .$ 

Secondly, we note that for a given  $p > \mathrm{QL}$ , we have  $y = (p, \mu, \sigma) \in \overline{\mathcal{C}} \implies P\left(X > U\right) \cdot p > \mathrm{QL}$ . This in turn implies that  $U < \mu + z_{1 - \frac{\mathrm{QL}}{p}} \cdot \sigma$ . We thus see that the integration range for  $\mu$  is  $U - z_{1 - \frac{\mathrm{QL}}{p}} \cdot \sigma < \mu < +\infty$ .

Given these considerations and the posterior distribution discussed above, and for  $x_m > 0 \in \mathcal{A}$ , we have

$$R_{C}^{*} = \int_{\overline{C}} g(y|x_{m}) dy$$

$$= \int_{p=QL}^{1} \int_{\mu=U-z_{1-\frac{QL}{p}}}^{+\infty} \frac{p^{\alpha_{1}-1} \cdot (1-p)^{\beta_{1}-1}}{B(\alpha_{1}, \beta_{1})} \cdot f_{\mu_{1}, \theta_{1}}(\mu) d\mu dp$$

$$= \int_{QL}^{1} \frac{p^{\alpha_{1}-1} \cdot (1-p)^{\beta_{1}-1}}{B(\alpha_{1}, \beta_{1})} \cdot \gamma_{C,1}(p) dp$$

with

$$\gamma_{C,1}(p) \coloneqq \int_{U-z_{1-\frac{QL}{2}}\cdot\sigma}^{+\infty} f_{\mu_{1},\theta_{1}}(\mu) d\mu.$$

## 3 Procedure for lot inspection on the basis of prior information

For  $x_m = 0$  (i.e.  $z_m = 0$ ), we have automatically have  $x_m \in \mathcal{A}$  and

$$R_C^* = \int_{\overline{C}} g(y|x_m) dy$$
$$= \int_{OL}^1 \frac{p^{\alpha_1 - 1} \cdot (1 - p)^{\beta_1 - 1}}{B(\alpha_1, \beta_1)} \cdot \gamma_{C,0}(p) dp$$

with

$$\gamma_{C,0}(p) := \int_{U-z_{1-\frac{QL}{p}} \cdot \sigma}^{+\infty} f_{\mu_0,\theta_0}(\mu) d\mu$$

(there is no posterior distribution for  $\mu$ ).

We now turn to the specific producer risk and the evaluation of the expression for  $R_P^*$  in Equation (2). For  $x_m \in \overline{\mathcal{A}}$  ( $\Longrightarrow x_m > 0$ ), we have

$$R_P^* = \int_{\mathcal{C}} g(y|x_m) \, dy$$

$$= \int_0^{QL} \frac{p^{\alpha_1 - 1} \cdot (1 - p)^{\beta_1 - 1}}{B(\alpha_1, \beta_1)} \, dp + \int_{QL}^1 \frac{p^{\alpha_1 - 1} \cdot (1 - p)^{\beta_1 - 1}}{B(\alpha_1, \beta_1)} \cdot \gamma_P(p) \, dp$$

with

$$\gamma_{P}(p) := \int_{-\infty}^{U-z_{1-\frac{QL}{p}} \cdot \sigma} f_{\mu_{1},\theta_{1}}(\mu) d\mu.$$

Finally, we turn to the global consumer and producer risks. For the situation under consideration here, and taking as acceptance limit  $A = U + 2 \cdot \sigma$ , the expression for  $R_C$  in Equation (3) can be written as follows:

$$R_{C} = \int_{p=QL}^{1} \int_{\mu=U-z_{1-\frac{QL}{p}} \cdot \sigma}^{+\infty} \int_{x_{m}=-\infty}^{A} \frac{p^{\alpha_{0}-1} \cdot (1-p)^{\beta_{0}-1}}{B(\alpha_{0}, \beta_{0})} \cdot f_{\mu_{0}, \theta_{0}}(\mu) \cdot f_{\mu, \sigma}(x_{m}) \, dx_{m} \, d\mu \, dp$$

$$= \int_{QL}^{1} \frac{p^{\alpha_{0}-1} \cdot (1-p)^{\beta_{0}-1}}{B(\alpha_{0}, \beta_{0})} \cdot \delta_{C}(p) \, dp$$

with

$$\delta_{C}(p) := \int_{U-z_{1-\frac{QL}{r}} \cdot \sigma}^{+\infty} \left( f_{\mu_{0},\theta_{0}}(\mu) \cdot \int_{-\infty}^{A} f_{\mu,\sigma}(x_{m}) \, dx_{m} \right) \, d\mu$$

As far as the global producer risk is concerned, the expression for  $R_P$  in Equation (4) can be written as follows:

$$R_{P} = \int_{p=0}^{QL} \int_{\mu=-\infty}^{+\infty} \int_{x_{m}=A}^{+\infty} \frac{p^{\alpha_{0}-1} \cdot (1-p)^{\beta_{0}-1}}{B(\alpha_{0}, \beta_{0})} \cdot f_{\mu_{0}, \theta_{0}}(\mu) \cdot f_{\mu, \sigma}(x_{m}) \, dx_{m} \, d\mu \, dp$$

$$+ \int_{p=QL}^{1} \int_{\mu=-\infty}^{U-z_{1-\frac{QL}{p}} \cdot \sigma} \int_{x_{m}=A}^{+\infty} \frac{p^{\alpha_{0}-1} \cdot (1-p)^{\beta_{0}-1}}{B(\alpha_{0}, \beta_{0})} \cdot f_{\mu_{0}, \theta_{0}}(\mu) \cdot f_{\mu, \sigma}(x_{m}) \, dx_{m} \, d\mu \, dp$$

## 4 Numerical example

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The following example is provided in order to illustrate the calculation of risks on the basis of the formulas provided above.

The upper limit of the acceptance interval A is defined as  $U + 2 \cdot \sigma$ .

The upper specification limit is U = 2.5 mg/kg.

Specific consumer risk values will be provided for two different values of  $\sigma$ , namely  $\sigma = 0.25$  and  $\sigma = 0.75$  and four different values of QL, namely QL = 0.1%, 1%, 5% and 10%.

The hyperparameters for the prior distribution for p (proportion nonconforming) are

$$\alpha_0 = 0.22$$
$$\beta_0 = 1.78$$

which corresponds to a mean p value of 11%.

The hyperparameters for the prior distribution for /mu (mean value of X) are

$$\mu_0 = 2$$
$$\theta_0 = 0.5$$

Since we are calculating specific consumer risks, we will only consider cases where the lot is accepted. Accordingly, for each value of  $\sigma$  and QL, we will consider the case that  $z_m=0$  and three cases of  $z_m=1$ , namely  $x_m=U-2\cdot\sigma$ ,  $x_m=U$  and  $x_m=U+2\cdot\sigma$ .

The resulting consumer risk values are provided in the following table. As can be seen, CR decreases as QL increases. This was to be expected since a larger QL means a higher proportion nonconforming is deemed acceptable. On the other hand, CR increases with  $x_m$  and with sigma.

## 4 Numerical example

$\sigma$	$z_m$	$x_m$	$\mathrm{QL}$	CR [%]
0.25	0	0	0.001	32.6
0.25	0	0	0.01	16.7
0.25	0	0	0.05	7.1
0.25	0	0	0.1	3.9
0.25	1	2	0.001	77.3
0.25	1	2	0.01	43.3
0.25	1	2	0.05	15.8
0.25	1	2	0.1	7.3
0.25	1	2.5	0.001	98.9
0.25	1	2.5	0.01	91.4
0.25	1	2.5	0.05	69.2
0.25	1	2.5	0.1	51.2
0.25	1	3	0.001	99.9
0.25	1	3	0.01	98.9
0.25	1	3	0.05	92.7
0.25	1	3	0.1	83.9
0.75	0	0	0.001	58.9
0.75	0	0	0.01	33.4
0.75	0	0	0.05	12.7
0.75	0	0	0.1	5.8
0.75	1	1	0.001	98.8
0.75	1	1	0.01	85.6
0.75	1	1	0.05	46.8
0.75	1	1	0.1	23.9
0.75	1	2.5	0.001	99.7
0.75	1	2.5	0.01	95.5
0.75	1	2.5	0.05	74.1
0.75	1	2.5	0.1	52.4
0.75	1	4	0.001	99.9
0.75	1	4	0.01	98.2
0.75	1	4	0.05	87.6
0.75	1	4	0.1	73.5

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# 5 Bibliography

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