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Process capability in raw milk pasteurization

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Abstract. Bacteria can lead to product quality and food safety issues especially in raw milk where higher levels of microorganisms can be caused by unclean equipment, improper sanitizing practices, inadequate udder preparation, mastitis infection or cooling problems. All these causes will have a great impact considering the hygienic quality o the processed milk. In this paper the total number of germs (TNG) was determined daily by testing milk tank samples after raw milk pasteurization sampled in 2013 from January to December. A statistically useful tool used for the analysis of the variability of the pasteurized milk bacteria showed that is of great importance. For the analysis of TNG variability was used EWMA (Exponentially Weighted Moving Average) control chart, which is typically used for individually observation done at different time intervals. Assessment of process capability was required to determine the relationship between natural process variation and the specified tolerances. Process capability of 0.33 is far from a desired value of 1. Unfortunately the UHT milk pasteurization process is directly related to the TNG from raw milk. This variability is impossible to be controlled by the processors but after our work can be concluded that raw milk variance is having an influence on free tolerance limits about 20 %. The use of EWMA and process capability control chart provided to be very useful statistical tools in the case of total number of germs monitoring from pasteurized milk, but a further research is needed to better understand how raw milk variability can influence the process.
Key Words: Raw milk, statistical process control, process capability, EWMA chart.

Introduction. Milk is synthesized in specialized mammary glands and is virtual sterile when is secreted in udder thru alveoli (Tolle 1980). Milk can be contaminated from three important sources: udder, milk equipment and storage facilities (Bramley & McKinnon 1990). Animal health and hygiene, housing and milking environment, cleaning and storage routine are all factors influencing the level of bacterial contamination in raw milk. At the same time temperature and milk time storage play an important role in bacterial multiplication (Murphy & Boor 2001). All these factors will influence the total number of germs (TNG) and the type of bacteria in raw milk. In what is considering the internal udder contamination, it is known that raw milk from healthy animals contains a TNG less than 10,000 bacteria per mL (Kurweil & Busse 1973).

Comparing with other factors influencing, the level of hygiene in milking is having a major influence in TNG increasing (Olson & Mocquat 1980). At the same time the water used in farms can be a source of different bacteria that can contaminate the equipment and/or the milk (Bramley & McKinnon 1990).

Increased bacterial contamination is often associated with occasionally actions due to an ineffective sanitation (Olson & Mocquat 1980; Thomas et al 1966) and/or an inefficient tank storage cleaning procedure (Thomas 1974). Time and temperature in milk storage will have an important role in reducing the level of contamination preventing the increasing of TNG at the farm level or at the dairy plant.

Generally, raw milk microorganisms are not heat resistant and will not survive to the pasteurization process. The type of increased bacteria in milk is related to the initial contamination with microorganisms (Bramley & McKinnon 1990). The microbiology considering milk and dairy products and industrial quality control became stable disciplines (Peleg 2002). As a consequence there were established methods and procedures to microbial milk sample analysis for human safety (Robinson 1990; Varnam

& Sutherland 1994; Hubbard 1996; Marth & Steele 1998; Walstra et al 1999; Stănescu 1998; Pentelescu & Mureşan, 2005).

Researches in dairy plants, shows a TNG with a great variability on a mean considered to be acceptable (Pentelescu & Mureşan 2008). Sometimes the appearance of some unexpected values can be due to different causes like the break of refrigeration system, human error etc.

Statistical process control (SPC) is a process monitoring method which uses problem-solving tools to achieve process stability through the reduction of variability (Quesenberry 1997; Mitra 1998; Montgomery 2009). The aim of SPC is to monitor the process and to distinguish normal variation from special variation (Luning & Marcelis 2009). Normal variation is due to natural variation or factors that are not well controlled. Special variations represent unusual variability in the process e.g. due to occasional extreme large seasonal differences in raw materials (Luning & Marcelis 2009).

Part of the SPC, control charts are more familiar with the use in animal production monitoring different aspects like bulk tank somatic cell counts in milk (Thysen 1993, Lukas et al 2005, Pentelescu & Mureşan 2008), estrus and diseases in dairy cattle (De Mol & Woldt 2001), or milk production (Van Bebber et al 1999). Niza-Ribeiro et al (2004) and Lukas et al (2008) provide capability indices for udder health measures of dairy cows.

To our knowledge a similar attempt to use statistical process control charts especially process capability tool to better understand variation in a raw milk pasteurization process from a microbiological point of view was not reported in the literature.

Material and Method. The total number of bacteria was determined daily by testing milk tank samples after raw milk pasteurization collected thru the year 2013 from January to December. To measures the total bacterial count present milk after pasteurization, samples were analyzed with Bactocount equipment (provided by Bentley Company) designed with the latest technology that uses fluorescent microscopy to analyze seventy milk samples per hour. The instrument is a completely automated system that consists of five modules: a computer, autosampler, incubator, filter and a counter.

For the analysis of TNG variability from UHT pasteurized milk was used control chart EWMA (Exponentially Weighted Moving Average), which is typically used for individually observation done at different time intervals. The EWMA is a statistic tool for monitoring the process that averages the data in a way that gives less and less weight to data as they are further removed in time. For the EWMA control technique, the decision depends on the EWMA statistic, which is an exponentially weighted average of all prior data, including the most recent measurement after Roberts equation (1959).

$EWMAt = \lambda Yt + (1-\lambda)EWMAt-1 for t = 1,2,\ldots,n$. Where:

- EWMA0 is the mean of historical data (target)
- Yt is the observation at time t
- n is the number of observations to be monitored including EWMA0
- $0 < \lambda \leq 1$ is a constant that determines the depth of memory of the EWMA.

The EWMAO was used especially to determine the upper and lower control limits control using the following formula:

$UCL = EWMA0 + ks_{ewma}$
$LCL = EWMA0 - ks_{ewma}$,

where the factor k is either set equal 3 or chosen using the Lucas & Saccucci (1990) tables. These monthly calculated control limits ware further used in process capability representation as limits specifications.

Assessment of process capability is required to determine the relationship between natural process variation and the specified tolerances. Thus the manufacturing process should be capable to make products within the set limitations (e.g. legislative limits or norms) (Luning & Marcelis 2009). The relationship can be presented by the following index:

Process Potential Index C_p (or process capability), which is the quotient of tolerated variation of Upper Specification Limit (USL), Lower Specification Limit (LSL) and the actual process variation, which is 6 σ assuming a normal distribution (Kehoe 1995).

C_p = (USL-LSL)/6 σ

C_p= 1 means that the process is capable, because the actual process variation is equal to the specified tolerances.

C_p> 1 means that the process is very capable

C_p< 1 means that the process is not capable.

For statistical interpretation and representation it was used statistical software Statgraphics Centurion XIV.

Results and Discussion. This procedure used was to create EWMA individuals calculations for every month to allow us to determine whether the data come from a process which is in a state of statistical control. The control charts were constructed under the assumption that the data come from a normal distribution with calculated means and different standard deviation. After EWMA calculations, the obtained monthly control limits were further used in process capability calculations. These limits were expressed in different range with a highest upper control limit in November (49751.9 TNB/mL) and a lowest control limit in August (25889.6 TNB/mL) (Table 1).

At the same time the Kolmogorov-Smirnov test which computes the maximum distance between the cumulative distribution of every month and the cumulative distribution function of the fitted normal distribution, was used to establish the fact that the data came from a normal distribution with 95 % confidence, since the smallest P-value amongst the tests performed was greater than or equal to 0.05 (Table 1).

Several capability indices have been computed to summarize the comparison of the fitted distribution to the specifications. Process Performance (P_p) and Process Capability (C_p) compare the distance between the specification limits to the area covered by 99.73 % of the fitted distribution (6-sigma for a normal distribution). One common index is Pp, which in the case of the normal distribution equals the distance between the specifications limits divided by 6 times the standard deviation. In our case, Pp have values between 0.21 and 0.41, which is usually considered to be not good. Since capability indices are statistics, they will vary from one sample of data to another. Given the monthly observations taken, the 95.0 % confidence intervals show how much these statistics might vary from the true values. C_p, which in this case equals to 0.33, measures short-term capability by calculating sigma from the average of the range shows us that process is not very capable.

The procedure was designed to compare a set of data against a set of specifications. The goal of the analysis is to estimate the proportion of the population from which that data come falls outside the specification limits. In this case, a Normal distribution was fit to a set of monthly observations in the variable DPM (Defects Per Million) of the fitted distribution which lies outside the specification limits with values between 212781 (July) and 524116 (August).

The free tolerance limit which comes from a normal distribution state that we can be 95.0 % confident that more than 81 % of the distribution lies between specifications (Table 1). This interval is computed from the smallest and largest data values. These results can be used to help select reasonable specifications for our process, if the current specifications are not being met.

Further was developed a process capability chart for the grouped data of all 310 observations, taking into consideration legislative recommendations transposed here in the upper specifications limit at 50000 TNG/mL (Figure 1). It is very important that products specifications and process parameters to represent both standards and tolerances.

Table 1

Milk pasteurization process analysis of TNG

	Jan.	*Feb.*	*Mar.*	*Apr.*	*May*	*Jun.*	*Jul.*	*Aug.*	*Sep.*	*Oct.*	*Nov.*	*Dec.*
Sample size	24	24	26	26	27	27	30	29	28	27	26	24
Std. dev.	3875.56	2966.91	5509.85	5316.63	4935.34	5353.53	4207.82	7158.09	5592.54	3517.46	4678.8	3448.11
Kolmogorov -Smirnov Test	0.74	0.92	0.75	0.87	0.97	0.48	0.95	0.77	0.65	0.99	0.16	0.53
UCL: +3.0	47176.3	42565.8	39066.8	39972.6	46414.4	44823.6	43376.1	41213.8	43526.8	40139.0	49751.9	49023.2
Centerline	44208.3	40291.7	35538.5	35557.7	42629.6	39555.6	38133.3	33551.7	39964.3	37240.7	46365.4	45708.3
LCL: -3.0	41240.4	38017.5	32010.1	31142.8	38844.9	34287.6	32890.6	25889.6	36401.8	34342.5	42978.9	42393.5
Sigma	2967.93	2274.13	3528.37	4414.89	3784.78	5268	5242.72	7662.11	3562.52	2898.25	3386.52	3314.83
Capability	3875.56	2966.91	5509.85	5316.63	4935.34	5353.53	4207.82	7158.09	5592.54	3517.46	4678.8	3448.11
Performance												
Cp	0.33	0.33	0.33	0.33	0.33	0.33	0.33	0.33	0.33	0.33	0.33	0.33
Pp	0.25	0.25	0.21	0.27	0.25	0.32	0.41	0.35	0.21	0.27	0.24	0.32
DPM	317306	317305	317312	317308	317313	317309	317307	317310	317311	317310	317313	317307
Capability	443785	443373	521929	406314	443158	325102	212781	284433	524116	409959	469188	336374
Performance												
Free Tolerance Limits (%)	81.66	81.66	82.97	82.97	83.56	83.56	85.11	84.63	84.11	83.56	82.97	81.66

To determine whether the data come from a process which is in a state of statistical control an EWMA chart for the year 2013 taking into consideration all 318 observations. The control chart was constructed under the assumption that the data come from a normal distribution with a mean equal to 39,741.3 and a standard deviation equal to 5,931.58. These parameters were estimated from the data. Of the 30 non-excluded points shown on the charts, none is beyond or upper control limits (Figure 1).

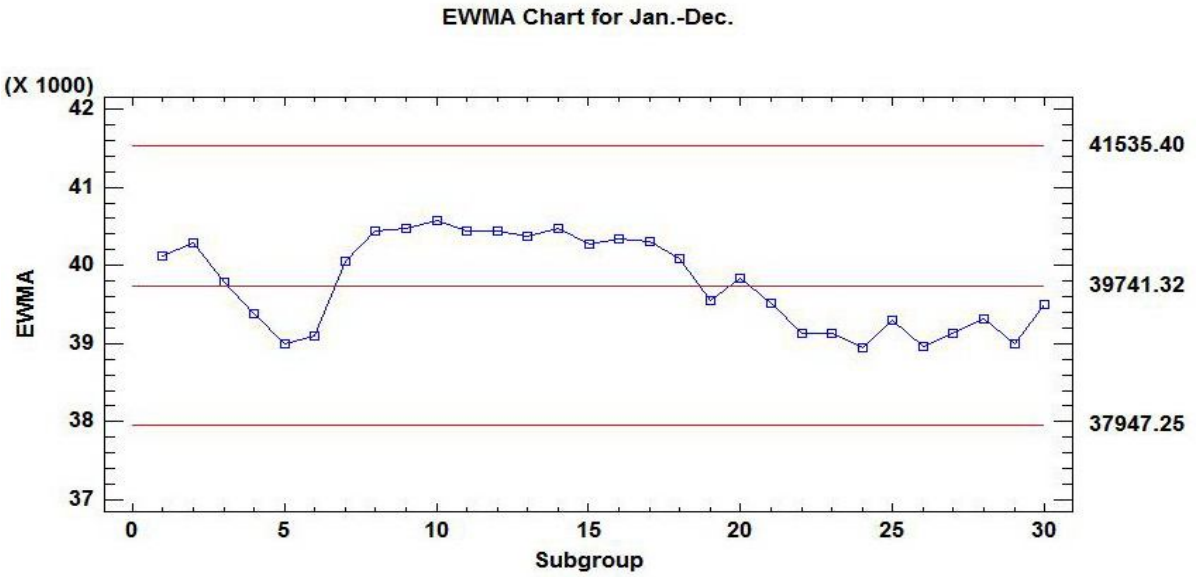

Figure 1. EWMA chart for the year 2013.

Several capability indices have been computed to summarize the comparison of the fitted distribution to the specifications. C_{pk} is an index (a simple number) which measures how close a process is running to its specification limits, relative to the natural variability of the process.

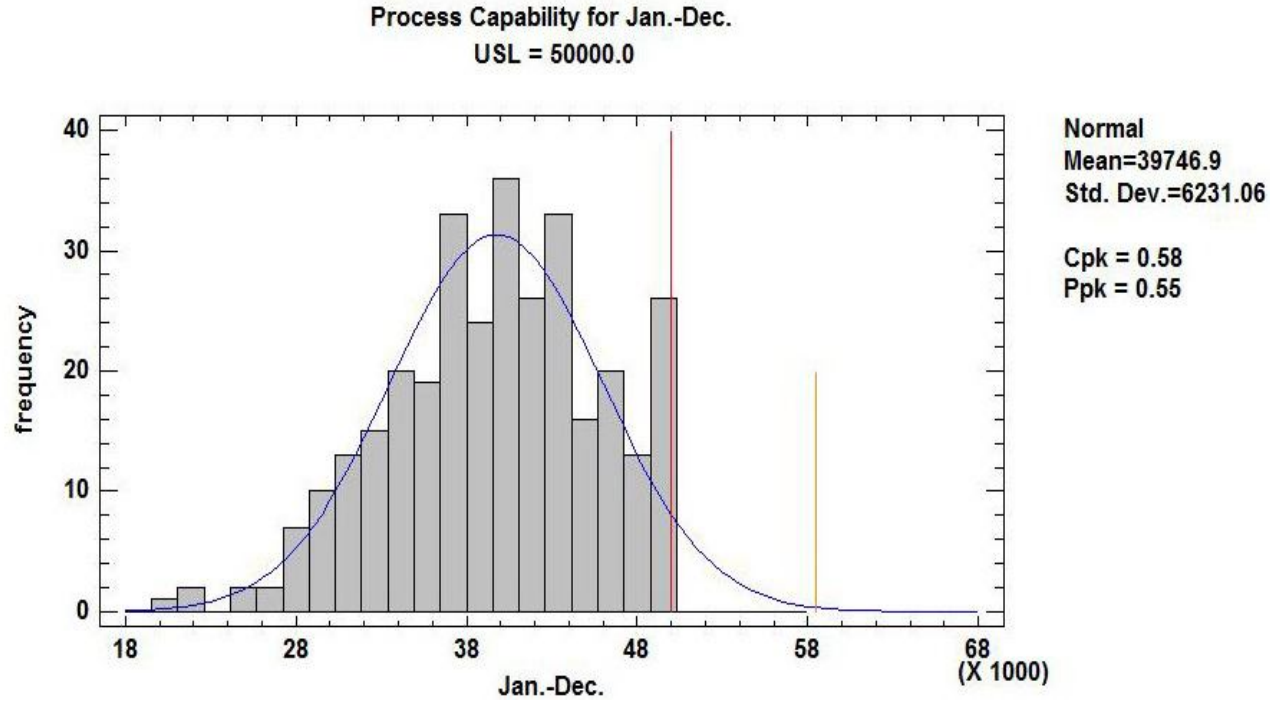

Figure 2. Process Capability for the year 2013, for an USL of 500,000 TNG/mL.

When the process is correctly centred, then the process potential index (C_p) and process performance index are equal ($C_{pk} = C_p$). However, in practice the C_{pk} is smaller that the C_p, because the process is not operating in the centre of the specification range. The indices often used in practice are: C_p is 1.67 or even 2.00 to be sure that the process variation fits within the specifications. A common value for C_{pk} is 1.33 Luning & Marcelis 2009). Since our Process Capability Index was only 0.58 we conclude that the UHT milk pasteurization process it is not in the middle of the tolerance range (Figure 2). Ppk Process Performance Index) is a one-sided capability index, which in the case of the normal distribution divides the distance from the mean to the nearer specification limit by 3 times the standard deviation. In this case, Ppk equals 0.55. Since capability indices are statistics, they will vary from one sample of data to another (Figure 2). The 95.0 % confidence intervals show how much these statistics might vary from the true values, given the fact that only 318 observations were taken.

Conclusions. Bacteria can lead to product quality and food safety issues. High bacteria levels can be caused by unclean equipment, improper sanitizing practices, inadequate udder preparation, mastitis infection or cooling problems. All these causes will have a great impact considering the hygienic quality of the processed milk. This value represents the number of bacteria that have entered the tank from all possible sources (Pentelescu & Muresan 2004). A statistically useful tool used for the analysis of the variability of the milk showed that is of great importance. The uses of process capability considering raw material proved to be a useful tool in the case of milk hygienic control.

At the same time the study of variability for UHT pasteurized milk established some control limit that could be further used in process improvement. Even if the process lies between specification limits we cannot talk about stability. Process capability of 0.33 is far from a desired value of 1. Unfortunately the UHT milk pasteurization process is directly related to the NTG from raw milk. This variability it is impossible to be controlled by the processors but after our work can be concluded that raw milk variance is having an influence on free tolerance limits about 20 %. For dairymen, raw milk bacteria counts represent an economic concern since in many cases the quantity of bacteria allowed in raw milk is directly related to bonus payments.

The use of EWMA and process capability control chart provided to be a very tool useful in the case of total number of germs monitoring from pasteurized milk, but a further research is needed to better understand how raw milk variability can influence the process.

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