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Statistical process control of the vertical form, fill and seal packaging machine in food industry

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Abstract

In food industry, high variability is quite common due to seasonality of raw materials and perishable products. Statistical Process Control (SPC) is an effective methodology to reduce variability and to make predictable processes. Literature still lacks of practical approaches of SPC implementation in food operations. Thus, this paper aims to propose a SPC method for quality control of a packaging process of fruit pulp sachets. This method is based on phase I and II study of P control chart for process stability and capability assessment. In phase I, special causes of variation were found and corrected in order to prevent against recurrence. After eliminating special causes of variation, the process capability has been reported as 2 sigma quality level. In phase II, an online monitoring procedure has been implemented and there was no special causes of variation in the packaging operation, assuring process stability.

Practical applications: The proposed method provides to the production supervisor a very powerful and straightforward tool for quality control. Basically, if at any daily production the fraction of defectives goes below lower control limit or above upper control limit, immediately, the supervisor has to conduct the procedure for detecting special cause of variation. The proposed method was very successful for assuring process stability during online monitoring. The fraction of defectives items was remained in statistical control while the ongoing monitoring was being performed.

1 | INTRODUCTION

The Statistical Process Control (SPC) is an essential methodology for variability reduction and problem solving. It is able to identify special causes of variation, eliminate/mitigate them, standardizing the process and assuring process predictability (Evangelista, Peruchi, Brito, Junior, & Rocha, 2020; Peruchi et al., 2020). Working with control charts and process capability indexes, the engineer can determine whether customer requirements have been met (Pable, Lu, & Auerbach, 2010).

In food industry, high process variability is expected and SPC methods can be adopted for quality control. The food industry is considered a sector of relevant importance for the economy (Costa, Godinho Filho, Fredendall, & Devós Ganga, 2021). Lim, Antony, and Albliwi (2014) show that the SPC benefits are variability reduction, food safety control and cost reduction. Bizuneh and Wang (2019) also state that SPC is of pivotal importance for food quality control. According to Hayes, Scallan, and Wong (1997), SPC implementation in the food industry is adequate to food safety standards and is integrated to the Hazard Analysis and Critical Control Point (HACCP). This is an approach for structuring a safety system to managing, handling and preparing food (Dzwolak, 2019). HACCP serves as a framework for a security system through the management, handling, and preparation of food (Hung, Liu, Peng, Hsu, & Yu, 2015). The use of SPC facilitates the application of HACCP, helps to control and monitor the process in real-time (Silva, Soares, Mazutti, Rosa, & Soares, 2019), through a systematic method, identifying and evaluating potential hazards (Yan et al., 2018).

Some examples of SPC studies applied to the food industry are shown as follows. Ebadi and Ahmadi-Javid (2019) used control charts to monitor service time at a fast-food restaurant. Fourie, Aleixandre-Tudo, Mihnea, and du Toit (2020) used SPC to monitor the phenolic extraction kinetics in red wines' fermentation. The research of Negiz, Ramanauskas, Çinar, Schlesser, and Armstrong (1998) studied the temperature variation in the milk pasteurization process. Srikaeo, Furst, and Ashton (2005) applied control charts and capability analyses to characterize and to control the quality of a wheat-based biscuit cooking process. Nigel and Grigg (1998) used $\bar{X}$ and R control charts for monitoring the package weight of fishing products and reducing the amount of defective packages. Du Nguyen, Tran, and Heuchenne (2019) proposed a new control chart, the VSI EWMA-RZ, to implement online monitoring and machine dosage controlling of products of flaxseed and pumpkin seed. Oliveira Silva et al. (2019) applied control charts to assess stability of cooking process of smoked sausages. As a result, process variability was reduced by 0.27% after implementing improvement actions in air speed and temperature parameters. Hung and Sung (2011) investigated defects such as shrinkage, unknown and crumbly material of a bakery process. They used Six Sigma tools such as Pareto Diagram, Tree Diagram, Process Mapping, Ishkawa diagram, $\bar{X}$ and R chart, as well as design of experiments (DOE) to reduce defects by 70% within 6 months. In another bakery example, Gauri (2003) studied the profit loss due to overweight of biscuit packages. The author used Pareto diagram, scatterplot and I-MR charts to reduce losses by 11.2% and to increase the process yield by 48.6%. Özdemir and Özilgen (1997) investigated defects of nut-based products in the cracking process. They applied p chart and DOE to adjust the process and to solve operational problems.

In the context of 4.0 industry, machine learning, machine vision and deep learning have been applied in food industry, enabling sustainable food production perspectives (Kakani, Nguyen, Kumar, Kim, & Pasupuleti, 2020). Artificial intelligence (AI) is pervading food systems helping to achieve a sustainable food industry. AI is applied in early stages of food systems, such as crop control through computer vision, machine learning, pattern recognition, robotics, in the development of demand-driven supply chains through pattern recognition—classification and prediction, machine learning, and natural language processing. AI can transform the food systems and support a transition to eco-friendly industry guaranteeing more health to the consumer (Camaréna, 2020).

Vining, Kulahci, and Pedersen (2016) argued that the food industry is a challenging area for quality engineering and SPC. The authors said that modern methods for improving processes have failed to solve problems of food manufacturers. Six sigma and SPC practices are among the least adopted by the food industry (Costa, Godinho Filho, Fredendall, & Ganga, 2020). In the systematic literature review of Lim et al. (2014), it is evident that the food engineers should apply SPC methods throughout their processes. The authors concluded that there is a gap of researches dealing with practical SPC methods focusing on facilitate and operationalize the implementation of SPC in the food industry.

Readiness factors of SPC application in food industry were identified, encompassing cultural organization, management support and operational aspects, such as measurement system and employees involvement (Lim & Antony, 2016). A roadmap to SPC implementation in food control was proposed by Abdul Halim Lim, Antony, Garza-Reyes, and Arshed (2015). The procedure was composed by five phases from quality control and assurance to continuous learning and quality improvement. The authors argued that the proposed roadmap facilitates food manufacturing companies to apply SPC at their processes.

Efforts have been undertaken to apply SPC in the food industry. Therefore, the main objective of this paper is to propose a SPC method for quality control of a vertical form, fill and seal (VFFS) packaging process of fruit pulp sachets. VFFS operation is extensively utilized to manufacture bags for packaging products such as confectionary, snacks, salads, pasta, liquids and so on (Desoki, Morimura, & Hagiwara, 2011; Matthews, Hicks, Mullineux, Goodwin, & Burke, 2011). For assessing process stability and capability, this method was conceived on phase I and II study of P control chart. In phase I, special causes of variation were found and corrected in order to stabilize the packaging process. After eliminating special causes of variation, the process capability was reported as 2 sigma quality level. In phase II, an online monitoring procedure was implemented and there was no special causes of variation in the packaging operation, assuring process predictability.

The remaining sections were structured as follows. In Section 2, the proposed method is theoretically discussed in details. In Section 3, the results are shown following the stepwise proposed procedure. In Section 4, the main findings are discussed and further research is suggested.

2 | STATISTICAL PROCESS CONTROL OF VFFS PACKAGING PROCESS

In this section, the proposed method for assessing VFFS packaging process stability, capability and online monitoring is described. This phase I and II control chart method has been conceived based on Montgomery (2009) and AIAG (2005), and it was adapted to the packaging process of fruit pulp sachets. Figure 1 shows the procedure for control charts implementation in the food industry. According to Montgomery (2009), in phase I a retrospective analysis is performed which serve primarily to define the current state of a process. Also in Phase I, the control limits are defined in order to conduct the online monitoring of process stability, which is the Phase II.

In the **first step**, a problem statement is provided, as well as the critical-to-quality characteristics must be stated. The **second step** data collection must be planned and the trial control limits should be calculated. According to (AIAG, 2005), data can be gathered from the entire population or sampling from that population in a representative way. Usually, larger samples provide greater chances of detecting small changes, though greater control/inspection costs. The practitioner must specify the following requirements when collecting the dataset:

i. Number of subgroups, m;
ii. Subgroup sample size, n_i;
iii. Interval time between samples, h;
iv. Distance of control limits from the center line, k (usually, $k = 3$).

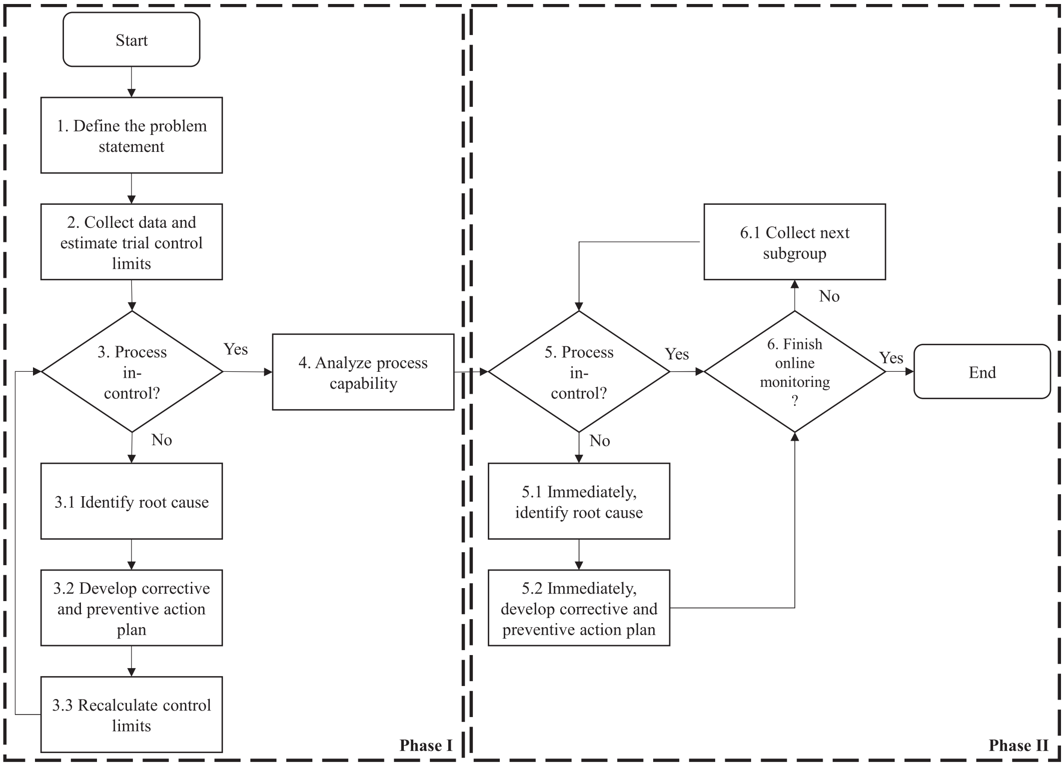

FIGURE 1 Phase I and II proposed procedure for assessing process stability, capability and online monitoring

The control limits (CL) serve as a reference to determine whether the process is stable. Depending on the data type and the sampling scheme, a particular control chart must be chosen (AIAG, 2005). In this study, the engineer is interested in monitoring the fraction of defectives, in which a p chart can be applied. Using Equations (1)–(3), upper (UCL) and lower (LCL) control limits as well as center line (CL) of a *p* chart are estimated as follows:

$$UCL_i = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n_i}} \quad (1)$$

$$CL = \bar{p} \quad (2)$$

$$LCL_i = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n_i}} \quad (3)$$

where

$$\bar{p} = \frac{\sum_{i=1}^{m} D_i}{\sum_{i=1}^{m} n_i} \quad (4)$$

and D_i is the number of defectives units in *i*th sample.

After estimating the trial control limits, the **third step** consists of assessing process stability. If the process is stable, there is a high probability (99.73%) that every subgroup will fall within the control limits (Montgomery, 2009). On the other hand, if any subgroup goes beyond these control limits, special causes of variation (SCV) might have occurred and they should be investigated (AIAG, 2005). After identifying the reason why SCV has occurred, corrective and preventive actions must be implemented. Eventually, control limits are recalculated excluding those subgroups with SCV (Atalay, Caner Testik, Duran, & Weiß, 2020).

In the **fourth step**, taking only in-control subgroups, a process capability analysis is conducted. Defects per million or parts per million (PPM) is the first process capability index which can be estimated as follows:

$$PPM = \bar{p} \times 10^6 \quad (5)$$

A process is considered capable with *PPM* as low as possible. Another interesting metric to determine process capability is the sigma quality level (or Z_{bench}). This metric can be estimated according to:

$$Z_{bench} = \phi^{-1}(1-\bar{p}) \quad (6)$$

where ϕ^{-1} refers to the inverse standard normal cumulative distribution with probability of $(1-\bar{p})$. A capable process would require large Z_{bench} to minimize the probability of producing nonconforming units.

After assessing process stability and capability in phase I, online monitoring procedure (**step 5**) is conducted as suggested in phase II at Figure 1. The control chart is used to monitor the process by comparing the fraction of defectives for each successive sample as it is drawn

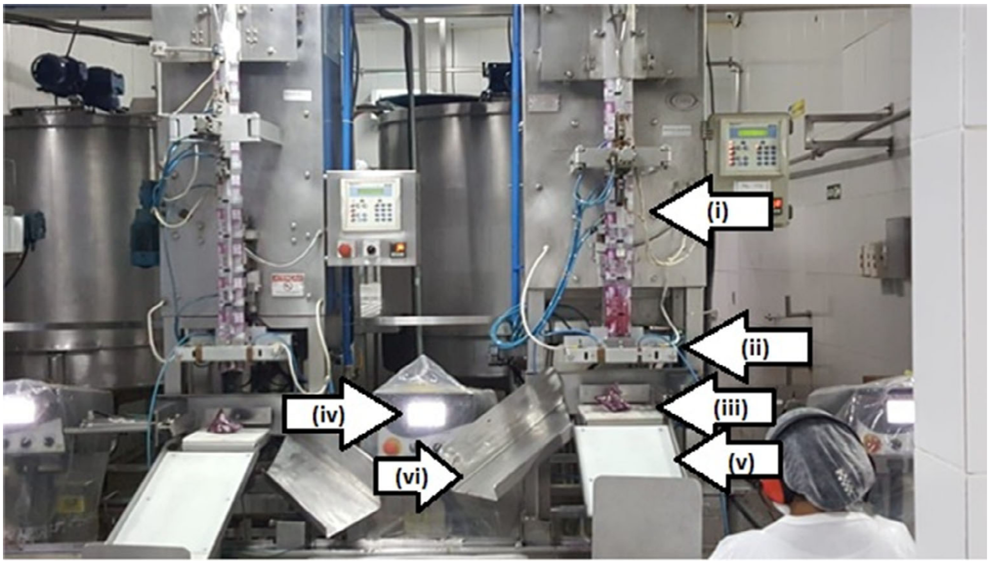

FIGURE 2 VFFS packaging process of fruit pulp sachets: (i) injector cables for filling the sachet, (ii) thermal sealing of sachets, (iii) weighing, (iv) sachet weight information, (v) conforming product line, and (vi) defective product line

TABLE 1 Subgroup sample size (n_i), defectives sachets (D_i), fraction of defectives (p_i) and variable control limits (LCL_i and UCL_i) of phase I study

				Before removing SCV		After removing SCV	
Subgroup	n_i	D_i	p_i	LCL_i	UCL_i	LCL_i	UCL_i
1	17,074	217	0.0127	0.0178	0.0244	0.0179	0.0245
2	14,143	341	0.0241	0.0175	0.0247	0.0175	0.0248
3	16,034	279	0.0174	0.0177	0.0245	0.0178	0.0246
4	18,431	349	0.0189	0.0179	0.0242	0.0180	0.0244
5	14,089	216	0.0153	0.0174	0.0247	0.0175	0.0248
6	20,591	168	0.0082	0.0181	0.0241	0.0182	0.0242
7	18,012	478	0.0265	0.0179	0.0243	0.0180	0.0244
8	14,250	264	0.0185	0.0175	0.0247	0.0176	0.0248
9	12,590	592	0.0470	0.0172	0.0249	0.0173	0.0250
10	14,230	332	0.0233	0.0175	0.0247	0.0176	0.0248
11	13,860	380	0.0274	0.0174	0.0247	0.0175	0.0248
12	14,735	270	0.0183	0.0175	0.0246	0.0176	0.0247
13	15,322	365	0.0238	0.0176	0.0246	0.0177	0.0247
14	14,552	275	0.0189	0.0175	0.0246	0.0176	0.0248
15	16,220	332	0.0205	0.0177	0.0245	0.0178	0.0246
16	15,360	368	0.0240	0.0176	0.0246	0.0177	0.0247
17	17,100	413	0.0242	0.0178	0.0244	0.0179	0.0245
18	15,145	345	0.0228	0.0176	0.0246	0.0177	0.0247
19	18,952	413	0.0218	0.0179	0.0242	0.0180	0.0243
20	13,222	312	0.0236	0.0173	0.0248	0.0174	0.0249
21	19,256	435	0.0226	0.0180	0.0242	0.0181	0.0243
22	18,110	354	0.0195	0.0179	0.0243	0.0180	0.0244
23	17,332	368	0.0212	0.0178	0.0243	0.0179	0.0245
24	14,235	280	0.0197	0.0175	0.0247	0.0176	0.0248
25	12,422	303	0.0244	0.0172	0.0249	0.0173	0.0250
26	15,154	310	0.0205	0.0176	0.0246	0.0177	0.0247
27	15,842	298	0.0188	0.0177	0.0245	0.0177	0.0246
28	16,249	354	0.0218	0.0177	0.0245	0.0178	0.0246
29	17,250	313	0.0181	0.0178	0.0244	0.0179	0.0245
30	12,125	221	0.0182	0.0172	0.0250	0.0173	0.0251

from the process to the control limits. If any subgroup goes beyond the control limits, immediately, SCV should be investigated. Just after that, corrective and preventive actions must be provided in order to avoid recurrence of that SCV.

Periodically, control limits must be revisited. Therefore, in **step 6** the practitioner has to decide whether the online monitoring should be finished. Otherwise, if the online monitoring is continued, a new sample is drawn from the process.

3 | RESULTS AND DISCUSSION

As seen in the proposed method, the **first step** is the problem statement. The problem is the excess of weight variation in sachets of fruit pulp in a food industry at Brazilian northeast. The VFFS model is the EI2000. The EI2000-BP models are vertical machines, fully automatic, for filling in flexible film-type packages of pasty products. They are built in a self-supporting structure in 304 Stainless Steel, with their functions and routines commanded by PLC (Programmable Logic Controller) and HMI (Human-Machine Interface), which are associated with Electronic and Pneumatic systems. Some technical characteristics of the machine are a production capacity of up to 3,000 units per hour, dosage volume from 100 g to 1,000 g, the power consumed 1.52 KW, working pressure 6 Kgf/cm^2, water consumption 50 L per hour. The VFFS process of sachets is the latest of the value stream so that the final product is ready, and it is where the problem lies. Sachet weight should be within the specification limits established by the company technical sector. The VFFS machine contains a weight control device which is preset by the head maintenance. If the sachet is less than 98 g, or more than 105 g, the machine automatically discards this sachet classifying it as defective. The process can be seen in Figure 2. Since this process produce defective items, a p chart can be used for assessing process stability, capability and online monitoring.

In the **step 2**, data collection was performed by the production supervisor and the data was directly obtained from the VFFS machine. Table 1 shows 30 subgroups which are 30 days of the entire production and defective items. The trial control limits have been calculated by Equations (1)–(4) and the result can be seen at Figure 3.

At the **third step**, process stability based on the trial control limits is evaluated. Due to the fact that there was no statistical process control applied to this process, several SCV were already expected as seen in Figure 3. Following the proposed method, the reason why every SCV was checked by using the procedure in Figure 4. Subgroups 1, 3 and 5 have been reported, by the head of the maintenance, as an electrical fault at the scale component which interconnects with VFFS machine. As corrective and preventive

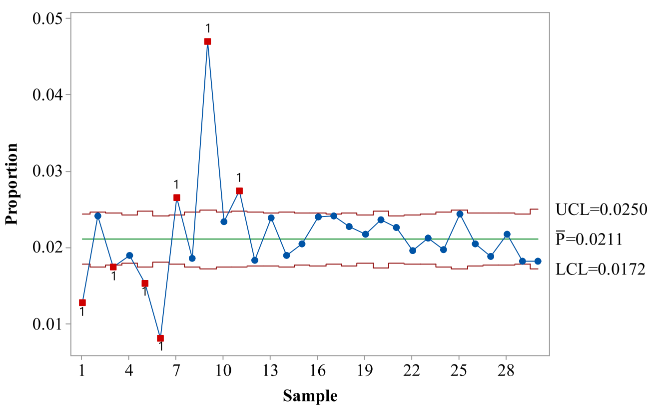

FIGURE 3 P chart using unequal sample sizes of defective sachets

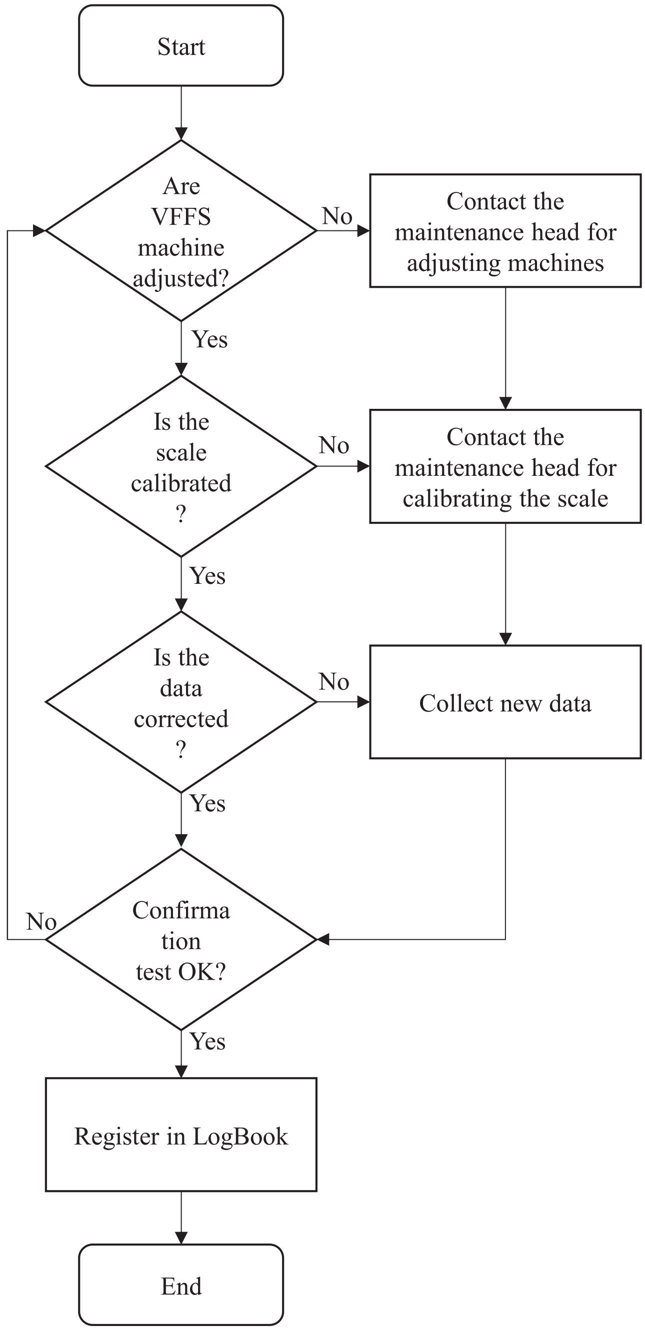

FIGURE 4 Out-of-control-action-plan for detecting special causes of variation

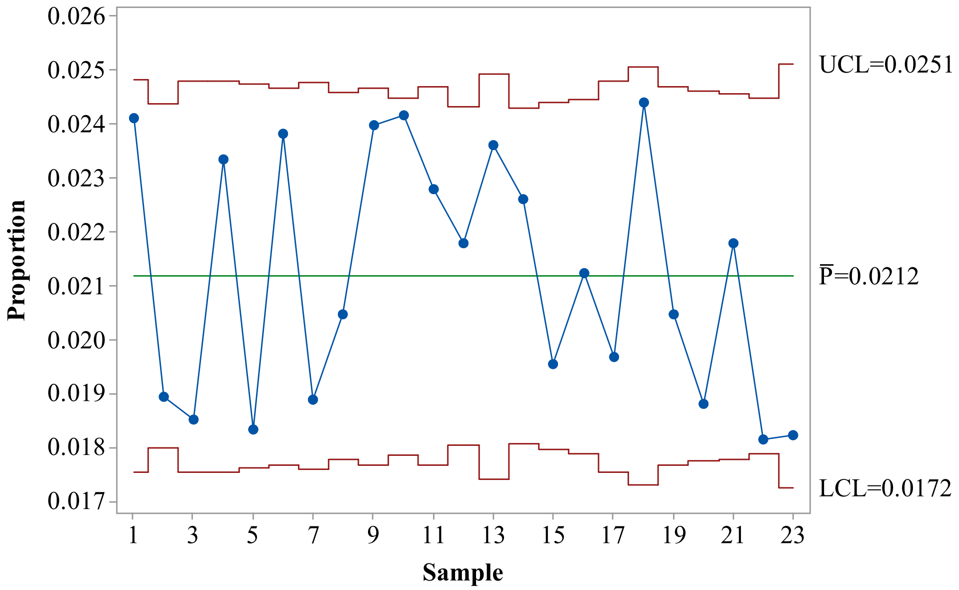

FIGURE 5 P chart of defective sachets after removing special causes of variation

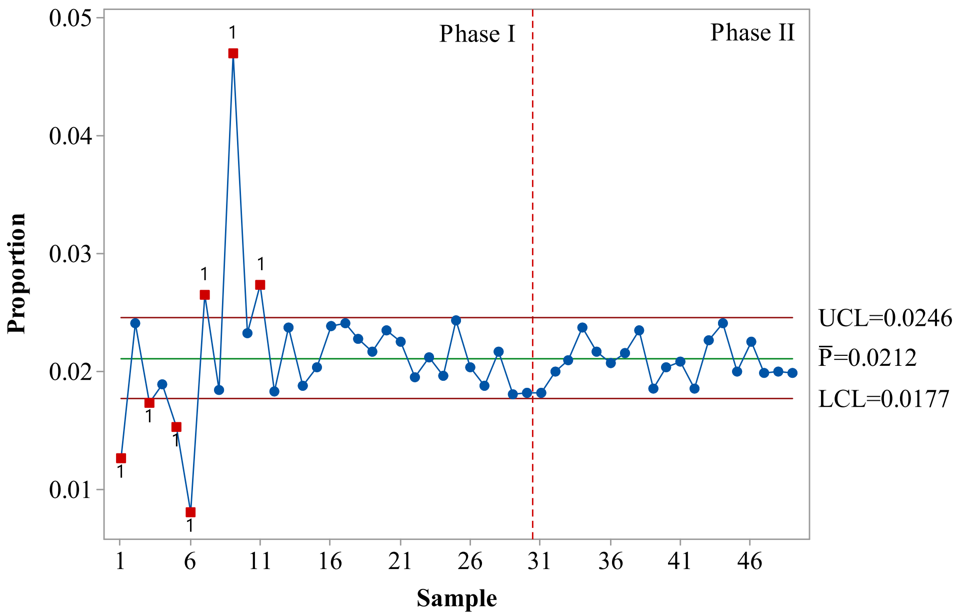

FIGURE 6 P chart of defective sachets for ongoing process monitoring

actions, this component has been replaced and a preventive maintenance plan considering its lifespan has been implemented, respectively. In subgroups 6, 7, 9, and 11, according to the company's logbook, there was a turnover of employees at the workstations. In fact, it takes some time for employees to be fully adapted to the operations of the new jobs. As corrective and preventive actions, the method of training employees was revised and improved in order to ensure better adaptation to new tasks. Finally, center line and control limits have been recalculated using Equations (1)–(4) and excluding the aforementioned subgroups with SCV, as seen in Figure 5. The remaining subgroups are in statistical control.

Turning now to the process capability analysis in **step 4**, *PPM* and Z_{bench} indexes are estimated. By using Equations (5) and (6), it is expected a sigma quality level of Z_{bench} = 2.03 and PPM = 21,200 defectives per million produced. This is a reliable estimate for process capability, since only in-control subgroups have been taken into account.

After assessing process stability and capability, the practitioner is interested in applying this control chart for ongoing process monitoring (**step 5**). The center line and control limits, based on phase I study, must be stated for phase II study. The control limits are distinct for each subgroup due to the variable sample size. Thus, a suitable approach is to take the average of subgroup sample sizes and replace n_i at Equations (1)–(3) by $\bar{n}$ as in Equation (7). The control limits for online monitoring can be seen in Figure 6.

$$\bar{n} = \frac{\sum_{i=1}^{m} n_i}{m} = 15{,}730 \text{ units} \tag{7}$$

TABLE 2 Subgroup sample size (n_i), defectives sachets (D_i) and fraction of defectives (p_i) of phase II study

Subgroup	n_i	D_i	p_i
31	16,321	298	0.0183
32	17,426	349	0.0200
33	16,545	348	0.0210
34	13,748	327	0.0238
35	17,221	374	0.0217
36	18,338	381	0.0208
37	14,854	321	0.0216
38	12,632	298	0.0236
39	16,349	305	0.0187
40	15,266	312	0.0204
41	13,478	281	0.0208
42	16,326	304	0.0186
43	17,420	395	0.0227
44	15,112	365	0.0242
45	18,934	379	0.0200
46	17,357	392	0.0226
47	18,456	367	0.0199
48	16,734	335	0.0200
49	13,100	261	0.0199

Now, the production supervisor possesses a very powerful and straightforward tool for quality control. Basically, if at any daily production the fraction of defectives goes below 1.77% or above 2.46%, immediately, the supervisor has to conduct the procedure for detecting SCV stated in Figure 4. The proposed method was very successful for assuring process stability during phase II study. As seen in Figure 6 and Table 2, the faction of defectives sachets was remained in statistical control while the ongoing monitoring was being performed.

Recently, an improvement project has been conducted in order to reduce the average faction of defectives sachets at the VFFS process. Therefore, as suggested by this proposed procedure at the **step 6**, the online monitoring study will be finished and the entire method in Figure 1 must be started over again.

It is essential to highlight that the literature is limited of studies dealing with food weight variation (Rai, 2008; Silva et al., 2019), sigma quality level (Z_{bench}) or p control chart applied at the food industry (Özdemir & Özilgen, 1997). This research has come up with a very successful SPC method implemented at a packaging process of fruit pulp sachets. The detailed approach was based on phase I and II control chart studies for assessing stability, capability and online monitoring of attribute processes.

4 | CONCLUSIONS

This research has proposed a statistical process control method for assessing stability and capability of packaging process of the food industry. The study has been applied to the vertical form, fill and seal packaging process of fruit pulp sachets. The method was based on the widely used phase I and II study of control charts. After conducting the proposed method, the main conclusions are highlighted as follows:

- The proposed method was straightforward and well organized so that the practitioner was able to perform tasks from the planning, execution, analysis and decision making stages;
- At phase I, by using retrospective dataset, process stability and capability were evaluated. Several special causes of variation (SCV) were found and mitigated by the aid of a standard procedure developed for this particular process (Figure 4);
- Phase I was essential not only to mitigate SCV, but also to report the process capability of 2 sigma quality level and specify the control limits utilized at the phase II study;
- At phase II, by using the control limits of LCL = 1.77% and UCL = 2.46%, the production supervisor was able to make an ongoing monitoring of fraction of defective sachets;
- Corrective and preventive actions have been so effective that no others SCV have been found at phase II study;

A pivotal issue is that the new proposed procedure (Figure 1) for assessing process stability, capability and online monitoring can be adapt to any food packaging process. On the other hand, the procedure for detecting SCV (Figure 4) is suitable only to VFFS packaging process. This innovative approach using attributes control charts can also be implemented along with food safety standards, such as HACCP.

Further studies would consist of improving process capability so that the likelihood of producing a defective sachet was extremely reduced. Additionally, the proposed procedure might be revisited integrating steps for process improvement by using design of experiments. Moreover, the proposed procedure might be implemented at other food packaging processes, packaging materials, products, and others.

AUTHOR CONTRIBUTIONS

José Rique Junior: Conceptualization; data curation; formal analysis; investigation; methodology; software; validation; visualization; writing-original draft; writing-review and editing. **Rogerio Peruchi:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing-original draft; writing-review and editing. **Paulo Rotella Junior:** Funding acquisition; methodology; project administration; resources; writing-review and editing. **Robson Dutra Pereira:** Formal analysis; methodology; validation; visualization; writing-review and editing.

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