GOBIERNO DE LA REPÚBLICA DE
GUATEMALA
MINISTERIO DE AGRICULTURA, GANADERÍA Y ALIMENTACIÓN

Guatemala, April 5th, 2019

Division of Produce Safety
U.S. Food & Drug Administration

1447
APR 8 '19 AM10:28

Dr. Nega Beru
Director
Office of Food Safety
Center for Food Safety and Applied Nutrition (CFSAN)
U.S. Food & Drug Administration

Dr. Samir Assar
Director
Division of Produce Safety
Center for Food Safety and Applied Nutrition (CFSAN)
U.S. Food & Drug Administration

Dr. Bery and Dr. Assar,

In compliance with the norm contained in Chapter 9 on Variances, in subparagraph P, numeral 1, of the Food Safety Modernization Act, I hereby send to you a Citizen's Petition of the Association of Independent Banana Producers of Guatemala (APIB by their acronym in Spanish), which contains a request for modifications to sections 21 CFR § 112.44 (a) (2) and 21 CFR § 112.43 (b) of subpart E of the Food Safety Modernization Act (FSMA).

The petition that accompanies this letter was made by APIB, after the Association presented arguments in this regard during multiple exchanges with representatives of the U.S. Food & Drug Administration, who guided APIB to proceed in the terms that were described in the initial paragraph.

These documents were prepared by APIB and are presented in English and Spanish, for the uses you may deem appropriate; they reflect findings that belong solely to said Association.

Best regards,

Dr. Nelson Ruano
Director
Food Safety
Ministry of Agriculture,
Livestock and Food
Government of the Republic of Guatemala

Cc.
File
Dr. Karen Killinger
Consumer Safety Officer
Division of Produce Safety
Center for Food Safety and Applied Nutrition (CFSAN)
U.S. Food & Drug Administration

Dr. Dave Ingram
Consumer Safety Officer
Division of Produce Safety
Center for Food Safety and Applied Nutrition (CFSAN)
U.S. Food & Drug Administration

GOBIERNO DE LA REPÚBLICA DE
GUATEMALA
MINISTERIO DE AGRICULTURA,
GANADERÍA Y ALIMENTACIÓN

Guatemala, 05 de abril de 2019

Division of Produce Safety
U.S. Food & Drug Administration

Dr. Nega Beru
Director
Office of Food Safety
Center for Food Safety and Applied
Nutrition (CFSAN)
U.S. Food & Drug Administration

Dr. Samir Assar
Director
Division of Produce Safety
Center for Food Safety and Applied
Nutrition (CFSAN)
U.S. Food & Drug Administration

Dr. Bery y Dr. Assar,

Por este medio, y en cumplimiento de la norma contenida en el Capítulo 9 sobre Variaciones, en el sub apartado P, numeral 1, del Food Safety Modernization Act, traslado a ustedes una Petición Ciudadana de la Asociación de Productores Independientes de Banano de Guatemala (APIB), que contiene una solicitud de modificaciones a los apartados 21 CFR § 112.44 (a)(2) y 21 CFR § 112.43 (b) de la sub parte E del Food Safety Modernization Act (FSMA).

La petición que acompaña este oficio fue realizada por APIB, luego que la Asociación presentara posiciones al respecto en múltiples intercambios con representantes del U.S. Food & Drug Administration, quienes orientaron a APIB a proceder en los términos que la presente refleja.

La documentación elaborada por APIB es remitida en inglés y español, para los usos que estimen convenientes y reflejan conclusiones que son propias de dicha Asociación.

Sin más que agregar, aprovecho la oportunidad para renovarles las muestras de mi más alta consideración y personal estima.

Atentamente,

Dr. Nelson Ruano
Director
Dirección de Inocuidad
Ministerio de Agricultura,
Ganadería y Alimentación
Gobierno de la República de Guatemala

Cc.
Archivo
Dr. Karen Killinger
Consumer Safety Officer
Division of Produce Safety
Center for Food Safety and Applied
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1 Detalle de pago del Transporte y Protección de Valor

Cobrar al: ☐ Remitente ☐ Destinatario ☐ Tercero

Pagar Aquí Su: ☐ Efectivo ☐ Cheque ☐ Tarjeta de credito

Protección del valor del envio ver al reverso

2 Enviado por (Remitente) Usar LETRA DE MOLDE

Número de cuenta

Nombre del remitente: Julio Merida

Referencia del remitente

Nombre de la compañía: Asociacion de Productores Independientes de banano

Dirección: 12 calle 1-25 zona 10 Edif Geminis 10 Torre Norte OF 1904

Código postal (Requerido según aplique): 01010

Teléfono (Celular Preferible): 23353507

Correo Electrónico: jmerida@apib.org.gt

3 Para (Destinatario) Usar LETRA DE MOLDE

☐ Comercial ☐ Residencial

U.S. Food and Drug Administration

Dockets Management
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

Código postal (Requerido según aplique): 20852

País: E.E.U.U.

Persona a Contactar

Teléfono (Celular Preferible)

Correo Electrónico

4 Piezas y Peso del Envío

El peso facturado es calculado del peso total y dimensiones

Número Total de piezas	Peso Total
1	0.5 KGS

5 Descripcion Completa del Contenido y Cantidad Usar LETRA DE MOLDE

Documentos

6 Sólo envíos por aduana (Non-Doc)

Número IVA/GST del Remitente

Numero de Licencia de Exportación

Government Export Number (whereilegally required)

Valor Declarado Para Aduanas (segun factura comercial)

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April, 2019

Citizen Petition

Request for Modifications to Section 21 CFR § 112.44 (a)(2) and Section 21 CFR § 112.43 (b) of Subpart E in Food Safety Modernization Act (FSMA)

To:

Division of Produce Safety
U.S. Food & Drug Administration

Dr. Nega Beru
Director
Office of Food Safety
Center for Food Safety and Applied Nutrition (CFSAN)
U.S. Food & Drug Administration

Dr. Samir Assar
Director
Division of Produce Safety
Center for Food Safety and Applied Nutrition (CFSAN)
U.S. Food & Drug Administration

Cc:

Dr. Karen Killinger
Consumer Safety Officer
Division of Produce Safety
Center for Food Safety and Applied Nutrition (CFSAN)
U.S. Food & Drug Administration

Dr. Dave Ingram
Consumer Safety Officer
Division of Produce Safety
Center for Food Safety and Applied Nutrition (CFSAN)
U.S. Food & Drug Administration

Dear Dr. Beru and Dr. Assar,

In this document, you can find the modification requests to sections 21CFR § 112.44 (a) (2) and section 21 CFR § 112.43 (b) of Subpart E of the Food Safety Modernization Act that we elaborate as a guild of banana producer, Association of Independent Banana Producers (APIB, for its acronym in Spanish) of Guatemala, with the support of the competent authority of Guatemala in matters of safety, Ministry of Agriculture and Livestock (MAGA, for its acronym in Spanish). The contents of this document are presented as follows.

CONTENT

I. REQUIRED ACTIONS

Requested Petitions:

1. **Modification section §112.44 (a) (2) of the Subpart E**:

112.44 (a) *"You must make sure that there is not detectable generic Escherichia Coli (E.Coli) in 100 milliliters (ml) of water of agricultural use and you should not use surface water without treatment for any of this purposes or activities:*

(2) Applied in any way that has direct contact with fresh agricultural products covered by the standard during or after harvest activities".

2. **Exclusion of Section § 112.43 (b) of the Subpart E:**

112.43 (b) *"You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its inrtended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable". Specifically its associated suggestion of keep ORP values between 700 and 825 mV in post harvest water: "the objective range to control cross-contamination in water with chlorine based desinfectants is 700 to 850 mV" (produce safety rule manual module 5 water for agricultural use: part 2: water used in post harvest, optional diapositive No. 62,2017, p. 50).*

II. DECLARATION OF CAUSE

The production of Banana in Guatemala is located and concentrated mainly in the area of the country known as the Costa Sur and /or Litoral del Pacífico. It is a border territory with the Pacific Ocean (South), with El Salvador (East) and Mexico (West) covering the territory of the departaments of San Marcos, Quetzaltenango, Retalhuleu, Suchitepequez, Escuintla, Santa Rosa and Jutiapa. With an altitud range between 0 and 3000 meters above sea level.

Banana farms are established between 0 and 500 meters above sea level, which places them in the lower part of the basins of the Pacific Ocean, where the surface water of the different rivers reaches their river mouth after they have passed, without receiving any type of treatment, for hundreds of villages upstream, so that when passing to the height of the banana farms, the water of these rivers in general, presents a degree of contamination mainly by *E.coli*, from the discharges of wastewater generated by referred population centers. Pollution that varies according to the river and the time of year.

It has even been claimed that at least 90% of surface waters in Guatemala are contaminated with feces (Mosquera, 2017, cited by Basterrechea et al., 2018: 386).

Therefore, as there are large rivers, for farms that use the water from the rivers as a source of irrigation, by means of engines installed on the riverbanks of rivers, from where the water

is pumped to be distributed to the irrigation systems by means of channels that have other engines for distribution, it is untenable and unaffordable to comply with the requirements of the Standard in its Section 21 CFR § 112.44 (b) and (2), which forces to give a treatment to these waters, to guarantee that it maintains a geometric mean (MG) of 126 or less colony forming units (CFU) in 100 ml of water and a statistical threshold value (VUE) of the samples of water with 410 or less generic *E.coli* UFC in 100 ml of water.

Being banana a crop where its fruit grows and unrolls during its entire cycle protected by a cover of nonwoven fabric (known as agribon) and a low density polyethylene bag, at a height above the ground of at least 1.50 m, with a sprinkler and / or micro-sprinkler irrigation system whose height does not exceed 0.60 m, a sprinkling angle of approximately 30 degrees and a harvest method that keeps the cluster covered until its arrival at the "bacadilla" [1], we see with concern that the Standard in its section 21 CFR § 112.44 (a) (2) establish that: *"you must not use untreated surface water (it is followed by the translation in Spanish)" "applied in any manner that directly contacts covered produce during or after harvest activities (it is followed by the translation in Spanish)", which would leave banana producers without being able to use the river water without treatment, as a source of irrigation, since the Standard in its Section 21 CFR §112.45 (a) (b) also establish that "if you have determined or have a reason to believe that your agricultural water is not safe or adequate sanitary for its intended use as required under CFR § 112.41 and /or 21 CFR §112.44 (a), you must inmediately discontinue that use(s) (it is followed by the translation in Spanish)"* Also quoted in its Section 21 CFR §112.43 (a) indicating that *"any method you use to treat agricultural water* [...*] *must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in 21 CFR § 112.44, as applicable (it is followed by the translation in Spanish)".*

Criteria that were also discussed at the meeting on water for agricultural use held on February 27 and 28, 2,018 in Covington, Kentucky, and whose results were recently published in comprehensive reviews in Food Science and Food Safety of the Institute of Food Technologists, where even the definition of "adequate sanitary quality" will remain under review by the FDA due to the need to support a quantitative standard, which can be affected by many variables such as water source, application, cultivation uses of the surrounding soil, among others.

As an Association of Independent Banana Producers (APIB) (For its acronym in Spanish), several studies have been conducted to determine the risk associated to the fruit may be exposed, during a direct contact with irrigation water without treatment, in order to

[1] "bacadilla": is a is a wide roofed area where all bunches of banana are received for inspection of the degree of maturity and quality; where the clusters remain hanging for variable times as they advance the tasks of the packing area (dehanded and selection).

evaluate the presence of *E.coli*, under various scenarios and conditions both in the field and postharvest, among these studies are:

1. **"Detecting the presence of *E.coli* by irrigation water in banana harvest bacadilla Section during different times, in dry season".**

Where the objective was to determine if there was a risk of contamination by *E.coli*, after the banana clusters were sprayed (intentionally) in a bacadilla with river water without treatment (345 CFU / 100ml), evaluation that was conducted while the clusters were in bacadilla from the min 0 of its arrival, until the min 120, in intervals of 30 min, being exposed to the environmental conditions of the place, as would normally be maintained in the daily operation; at a temperature of 30 to 32.2 °C and relative humidity from 62.6% to 74.7% according to information from the meteorological station located in the farm where the study was conducted, during the time it lasted (approximately 4 hours, from 10:00 a.m. to 14:00 hrs).

The results obtained allowed to determine that 100% of the samples evaluated, 85% of them showed results of non-detectable *E.coli*, against 14% of the samples that did show the presence of the bacteria. Results that confirm the natural capacity of the banana peel to limit the permanence of the bacteria in the fruit. It should also be considered that this happens before several critical control points: a) wetting the fruit with water extracted from the well, chlorinated between 1.5 and 3 ppm, b) fumigation with fungicides in specialized chambers, c) refrigerated transport from 15 to 18 days in containers with temperatures between 17-18 °C.

It is worth mentioning that for the study, the bunches evaluated were sprayed entirely with river water without treatment, which under normal conditions does not occur, because the bunch is harvested and transported to the bacadilla, without removing the agribon and the polyethylene bag. Which provides protection, so the risk of direct contact with irrigation water during its transfer to bacadilla is relatively low.

In addition, it is important to point out that after arriving at a bacadilla the bunches enter directly to the post-harvest process, where they are immersed in tanks that receive water with residual chlorine concentrations ranging between 1.5 and 3.0 mg / l, and that are monitored every hour using colorimetric kits, filling the respective register. As well as the set of good manufacturing practices that producers have implemented in their quality management system to ensure the production of an innocuous fruit.

The study was conducted in the dry season because it is the season of the year when more water is required for irrigation for cultivation, coming from the rivers through direct pumping. Considering also that the rainfall dilution factor is lower in the currents at this

time and that the temperature conditions are more favorable for the development of E.coli according to their thermophilic preferences.

2. **"*Determination of the presence of E.coli in the peel and edible part of the banana and evaluation of its growth during the process of post-harvest and storage at a controlled temperature*" (Currently in the process of being published in the indexed journal of the Faculty of Chemical Sciences and Pharmacy of the University of San Carlos de Guatemala, ISNN 2070-8246 and 2224-5545 and admitted to participate at IX World Banana Summit (CMB, for its acronym in Spanish), Ecuador, April 9th to 11th , 2019.)**

The results obtained in the study allowed to determine that even if you have a contaminated peel by *E.coli*, the inner part (edible part) of the fruit, does not represent a risk of contamination by *E.coli* that endanger the safety of the pulp or the health of consumers. Being demonstrated that the risk of cross microbial contamination from the water to the banana is low when the peel has no mechanical damage and that in addition, the state of maturation of the banana (green), contributes to maintain the conditions of rigidity of the peel, giving it a condition of impermeability that fulfills an important function in the safety of the fruit, mainly in its edible part, protecting it from contamination by *E.coli* up to 30 min after being immersed in water contaminated with 60000 CFU / ml of *E.coli*.

At the same time it was determined that during the permanence of the fruit in stowage (day 1) and in the early hours of sampling (10:18, 12:30, 14:40, 16:44 hours) at an average temperature of 26 °C, the twenty samples made to banana peels did not show presence of *E.coli* . This result was repeated in both the five samples taken on day 4 and in the five samples taken on day 18, after having stored the boxes in the cold room at a controlled temperature between 17°C and 18 °C for a total of thirty negative samples.

In fact, infiltration test on fresh products have also been very common to observe through stains, how much the contaminated water penetrates the fruit. In case of bananas, The Association of Independent Banana Producers (APIB), in order to check visually and in a simple way the permeability of the banana peel, at the beginning of the year 2018 using a strong dye, the infiltration risk of the banana towards the pulp was evaluated. Concluding that no visual evidence was found that the dye had infiltrated through the peel after being exposed and immersed in it for two hours.

With the results obtained in the study, it was also possible to determine the absence of E. coli in the banana peel that was in the stowage area for 7 hours and then stored for 18 days under temperatures in the range of 17 to 18 °C to simulate the period of transport and subsequent storage. These results were maintained for the 30 swabs performed during three sampling days (day 1, day 4 and day 18). It was evidenced, therefore, that by having free E.coli bananas in the stowage area, it is guaranteed that there is no growth of bacteria during storage, even though conditions are present that may enhance their development.

In short, the results allowed to demonstrate the capacity of the banana, mainly by the characteristics of its peel at a biochemical level - such as the antibacterial and antioxidant activity that occur in the green banana peel - to resist the entrance of the bacteria to its edible part. Which adds value if it is considered that historically there has never been any case reported of contamination by *E.coli* in banana.

The results of both studies have allowed to determine and confirm that the banana is a low risk crop, which does not represent a danger to the health of the consumers, since an innocuous fruit is being produced due to the good practices of field and postharvest implemented by the banana farms, favored mainly by the physico-chemical characteristics of the banana peel, which give a condition of impermeability to bacteria such as *E. coli*, even after the fruit is exposed (intentionally and under controlled conditions, as detailed in one of the studies) for up to 30 min in water contaminated with *E.coli*, at the rate of 60000 UFC/ml. Values that at the time , are much higher than those reported in rivers at the Costa Sur of Guatemala.

Results that are similar to those obtained in onion, where it was demonstrated that *E. coli* was not detectable in the 15 days after irrigation (Wright, Feibert, Reitz, Shick & Waite.Cusic, 2018, cited by Wall, G., et. al., 2019: 8), so that the physical characteristics of the banana and the productive practices implemented should be considered in the risk assessment to carry out the modifications to the current standard of the Produce Safety Rule.

Given that the scientific basis of logarithmic death rates (0.5 log / day) and its variability to consider various pathogens, climates and products (Wall, G., Clements, D., Fisk, C., Stoeckel, D ., Woods, K. & Bihn, E., 2019: 6) the study of APIB both in trawl and in refrigerated storage could be related to this type of corrective measure suggested by the FDA, since although it did not provide logarithmic death rates defined, allowed to determine how the presence of the bacteria behaves with the passage of time in hours, days and weeks.

About petition 2, regarding to Section § 112.43 (b) of subpart E and the suggestion of the standardized curriculum designed by the producer safety alliance to implement the Food Safety Modernization Act (FSMA) which proposes values of 700 to 825 mV in chlorine-based disinfectants to monitor water. It can be added that in fact, the addition of chlorine is one of the most commonly preventive measures used to eliminate pathogens in fruit washing water. The use of water in the postharvest phase of banana is useful both to protect the bunch during the discharge and to wash it, using as values for its control concentrations of free chlorine between 1.5 and 3 mg / l.

The criterion for the addition of chlorine is very varied in terms of concentration, for example: Mencarelli (2004), talks about adding 75 to 125 ppm sodium hypochorite, to reduce the possible decomposing organisms; Arias (2007), indicates that the water used

must contain active chlorine in concentrations of 100 to 200 ppm; D. Robinton and Mood (1967), in their results for three microorganisms: *E.coli* (ATCC 11229), streptococcus faecalis (ATCC 8043) and Staphylococcus Aureus (ATCC 65538) determined that under conditions of the test and in absence of acid cyanuric *E.coli* was rapidly destroyed (30 seconds) by concentrations of calcium hypochlorite, trichloroisocyanuric acid and potassium dichloroisocyanurate, providing 0.11 mg/l of "free" or available chlorine. The Guatemalan Standard COGUANOR NGO 29001: 2013, states that the maximum acceptable, safe and desirable limit of free residual chlorine, in the furthermost points of the water distribution system is 0.5 mg/l, after at least 30 min. of contact, at a pH lower than 8.0, in order to reduce by 99% of the concentration of *E. coli* and certain viruses, also indicating that the maximum permissible limit is 1.0 mg/l. Such studies and results are relevant if it is considered that in the context of the Food Safety Modernization Act the washing water must be drinking water and *E.coli* is not detectable.

Currently, with the FSMA law and after the numerous tests that since the year 1968 have been conducted to determine that the key indicator to assess microbiological quality of water is the ORP and not the concentration in parts per million (ppm) of free chlorine, it was determined that the recommended level of ORP should range between 650 and 750 mV (Steinier, 1985) and that, with this ORP bacteria such as *E.coli* 0157:H7 and species of salmonella can die within thirty seconds of exposure (Suslow, 2004) or less, the Plant Health State Committee of Baja California (s.f.) indicates rages of 10 to 20 seconds. Hence, the standardized curriculum designated by the Produce Safety Alliance to implement the FSMA law suggests values of 700 to 825 mV in chlorine – based disinfectants to monitor water (Produce Safety Alliance, 2017).

However, after multiple tests in banana by the producers and APIB, between the months of January and June of 2018, using calcium hypochlorite tablets, sodium hypochlorite in liquid form, organic chlorine (PROVITAB 3®) in tablets, organic chlorine (PROVITAB 3®) granulate, peracetic acid and hydrogen peroxide, it was determined that reaching an ORP in the range of 700 to 825 mV is unaffordable, besides that such a high value is not necessary, when it has been demonstrated that the fruit is impermeable and that the fruit maintains its safety even after being packed, following what is ruled by the Guatemalan Standard COGUANOR NGO 29001:2013, which states that the maximum acceptable, safety and desirable limit of free residual chlorine, at the furthest points of a drinking water distribution system is 0.5 mg/l.

Therefore, through this petition whereas the possibility that the Produce Safety Rule is modified to consider new standards is open; in the absence of clear guidelines, scientific support and alternatives to give clarity and flixibility to different producers (Wall, G., et al., 2019: 11) and as this is defined and remains in participatory discussion, banana producers

they do not wish to remain in the uncertainty for which reason they come to propose this modification; and based on the above, it is requested that:

a) The irrigation of banana crop is not limited by the use of water from rivers without treatment. Considering that neither the State of Guatemala nor the different Municipalities of the country, have managed to comply with the treatment of their wastewater, mainly due to the high cost associated with this type of projects and, also, through the implementation of good practices on the farm, an innocuous production of bananas has been guaranteed to this day,

b) The form of water quality monitoring does not exclude the determination of residual chlorine in post-harvest water and considers the concentrations of this disinfectant agent to be between 1.5 and 3 mg/l.

Both requirements are based on the natural characteristics of the fruit and good practices in the post-harvest field, which the banana producers conduct to guarantee an innocuous banana free of contamination by *E. coli*. Being the greatest guarantee, as shown by the aforementioned studies, the safety maintained in the bananas packaged and transported for final consumption.

It is also important to mention that currently all the producing farms that are members of the Association of Independent Banana Producers (APIB) of Guatemala, have the Global Certification G.A.P. which is audited and reviewed annually, also evaluating aspects of safety. Additionally, APIB conducts two annual internal control audits in its associated companies, assigning a specific section to safety and good agricultural practices.

On the other hand, it is also important to mention that the farms are required by law to maintain annually updated their Operating Sanitary License issued by the Ministry of Agribusiness and Livestock (MAGA), which is the competent National authority in the matter according to Governmental Agreement No. 72-2003.

Guatemala is the third largest exporter of banana worldwide behind Ecuador and the Philippines (Jiguan, 2019) and 95.4% of banana production in the country is exporting to the United States (Economic and Commercial Office of Spain in Guatemala, 2016:6) However, despite these important export volumes, it is stated that, historically, there have been no reported cases of *E. coli* contamination in banana, according to Rushing J., Bihn. , E., Brown, A., Hill, T., Jones, J., Martin, Y., McGarr, S., Saltsman, J., Smith, M., Suslow, T., and Walsh, C. (2012:16):

(...)Although large water ponds can be used for long periods, the risk of infiltration is minimal because the bananas have a positive internal pressure that pushes the latex from the cut stems (...) Human diseases have not been associated with consumption of fresh bananas.

For all these reasons, APIB agrees with what was stated by the participants of the meeting on water standards for agricultural use, who expressed the importance of the risk assessment considering the type of crop and the method of application of the water: "participants at the water summit felt strongly that assessing risk should also include application method and crop type "(Wright, Feibert, Reitz, Shock & Waite-Cusic, 2018, cited by Wall, G., et., al., 2019: 9).

III. ECONOMIC IMPACT

APIB agrees with the idea presented in the document meeting report: Key Outcomes from a collaborative summit on Agricultural water Standards for Fresh Produce: "The cost of implementing practices is a crucial factor when determining the value (for example, to allow business to remain viable) and feasibility of the current water testing requirements in subpart E, and is directly related to the variability in production practices, Water sources, and scale of farms around the country" (Wall, G., Clements, D., Fisk, C., Stoeckel, D., Woods, K. & Bihn E., 2019:5). So the following is the impact of the associated costs:

1. Sampling and microbiological profile

The economic consequences of the water quality standard proposed in §112.44 (a) (2) can be quantified from the construction of the microbiological profile requested in § 112.44 (b) for water sources for agricultural use.

FDA reports that the cost of a sample conducted to quantify *E.coli* in water can vary between USD $ 87.30 and USD $ 120.05 (Wall, G., Clements, D., Fisk, C., Stoeckel, D., Woods, K. & Bihn, E., 2019: 5) In fact, in Guatemala to perform the test by method 1103.1 EPA-821-R-10-002, contemplating transportation costs and sampling time is quoted at approximately USD $ 150. It should be considered in addition, most farms operate with two or more sources of surface and underground water. A single sampling campaign for a banana farm could cost USD $ 600 and should be repeated five times a year, meaning around USD $ 3000.

Following the suggestions that were discussed during the meeting on the standards of agricultural use, APIB joins the intention that several farms can share the expenses related to our microbiological samples destined to characterize the same body of water and manage results obtained by districts of irrigation organized. In fact, at least 5 member companies of APIB operate using the figure of an irrigation district, which would allow them to obtain information on the same body of water that they all use to irrigate their plantation.

2. Water Treatment for Irrigation

It is unaffordable to treat surface water from rivers, and before a notorious legal void, the issue is even more complex in Guatemala. Currently, water quality is largely defined by the Regulation of Wastewater Discharge and Reuse and Sludge Disposal; Government

Agreement 236-2006. However, at the national and municipal levels especially, compliance is deficient and null in some cases. What makes it impossible to join efforts to enforce the Law.

Banana producers in Guatemala see the issue with concern because, although they are willing to comply with the Standard, this type of conditions limits their implementation, since the investments have already been millions in the different farms and also assume a cost for the treatment of water from the river for irrigation, being a subject of country that historically has not been taken care of, puts at risk even their own operations.

The prices of various treatment systems can range from USD 400 to USD 3000 per m^3. The investment for the conditioning of wells can vary between USD 300 to USD 750 per meter drilled, also joining the energy costs for pumping (1 HP is required for every meter of depth) and subsequent water treatment.

On the other hand, the disinfection of water for use in postharvest handling is indisputable, however, reaching the suggested ORP values (700-825 mV) produces a significant increase in the cost of the daily operation of the banana packing.

Between January and June 2018, different banana producing farms of APIB conducted tests to stabilize the ORP at the values previously mentioned (700-825 mV). The tests included the use of calcium hypochlorite in tablets, sodium hypochlorite in liquid form, organic chlorine (PROVITAB 3®) in tablets, organic chlorine (PROVITAB 3®) granulate, paracetic acid and hydrogen peroxide. The results showed that, if it was desired to continue using calcium hypochlorite or sodium hypochlorite to reach the required ORP values, the consumption of the chemical increased about seven times more than what was commonly used, which increased costs by 100% and 600% depending on the chemical characteristics of the water (iron, magnesium, hardness) also exposing a potential "burned" of the fruit, reducing its quality.

On the other hand, when using other disinfecting agents such as paracetic acid, hydrogen peroxide or organic chlorine, daily operating costs increase by 700 to 1000% (De León et al., 2018).

The objective of the guild is to comply with the Food Safety Modernization Act and guarantee an innocuous banana for the consumer, which is being achieved through the implementation of good practices in the field and in postharvest, so that investments in water treatment, would not change said production system, but it would damage the ability of producers to sustain decent jobs for the more than 30,000 direct employees who benefit from banana plantations members of APIB.

IV. ADDITIONAL INFORMATION

Both the studies conducted by the Association of Independent Banana Producers (APIB) and the corresponding laboratory analysis are available for review and analysis if required.

V. FRAMEWORK

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