Reviews

Food Safety Modernization Act Produce Safety Rule Compliance for United States Hard Cider Producers Using Ground-harvested Apples

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SUMMARY. Apples (*Malus domestica*) are considered covered, or “nonexcluded,” produce under the Food Safety Modernization Act Produce Safety Rule. The rule states that fruit that has unintentionally come in contact with the ground may not be used for human consumption unless there have been sufficient processing steps to reduce the risk of human pathogens in the final food product. Cider apples destined for hard cider production in many regions have traditionally been harvested at full ripeness when the fruit naturally drops or is easily shaken off the tree. This work reviews the status of cider apples under the Produce Safety Rule, presents the human pathogens of concern with usage of ground-harvested fruit, and describes recommendations, including processing steps, for cider apple growers and cider producers so they can ensure that their product is safe and that they are complying with the rule.

In the United States, both fresh and fermented apple juice may be called “apple cider,” but “cider” here refers to the alcoholic, fermented “hard” cider product. Food safety considerations regarding apple juice or “sweet cider,” the nonalcoholic, unfermented product, is not addressed in this review, as they have been previously reviewed and addressed elsewhere (Vojdani et al.,

2008). Cider production is currently a small segment of the alcoholic beverage industry with a national size equaling $\approx 1.3\%$ of U.S. beer production. In other cider-producing regions, such as the United Kingdom, France, and Spain, the size of the cider industries are 22%, 4.8%, and 2.0%, respectively, relative to beer (Brager and Crompton, 2017). However, despite the relatively small size of the U.S. cider market, this beverage category has experienced significant growth in recent years,

with much of the growth in the craft cider markets (Brager and Crompton, 2017).

A wide variety of apple cultivars, including dessert and culinary apples, may be used for cider production, resulting in countless styles and flavor profiles. Cultivars may be selected based on their sugar profile and sugar content, acids, tannins, aroma profiles, or other factors important for sensory evaluation; however, most ciders are made from dessert or culinary apples that may be destined for multiple markets, including fresh consumption and juice production. Traditional, European-style ciders contain cider-specific apple cultivars that have high concentrations of tannins that make them valuable for lending bitter and astringent sensory properties to the cider deemed as “bittersweet” or “bittersharp” (Barker, 1903). Unlike dessert and culinary apples, cider cultivars do not serve alternative purposes and are therefore destined for cider processing via alcoholic fermentation. These cultivars are in relative short supply and, therefore, are more expensive in the United States, so blending with and use of dessert and culinary apples is necessary for cider production.

Although apples in the United States are typically hand-harvested before full ripeness to allow for long-term storage of fresh market apples, it is not uncommon in other countries to allow fruit destined for cider production to fully ripen on the tree. Once fruit is fully ripe, it will drop naturally or by mechanically shaking the tree to encourage fruit drops. The fruit is then mechanically swept up and collected for processing (Lea, 2015). Because of high labor costs and workforce shortages, this “shake and sweep” method is advantageous and may also result in cost savings compared with hand-harvesting.

Despite these advantages, there are some important tradeoffs to consider. Because of the bruising and

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Units

To convert U.S. to SI, multiply by	U.S. unit	SI unit	To convert SI to U.S., multiply by
29.5735	fl oz	mL	0.0338
1	micron(s)	μm	1
28.3495	oz	g	0.0353
1	ppm	$\text{mg}\cdot\text{L}^{-1}$	1
$(^{\circ}\text{F} - 32) \div 1.8$	$^{\circ}\text{F}$	$^{\circ}\text{C}$	$(^{\circ}\text{C} \times 1.8) + 32$

damage that occurs when fruit is shaken and allowed to drop from the tree, fruit must be processed immediately, as it will rot more rapidly (Alexander et al., 2016; Miles and King, 2014). Furthermore, fruit contact with the orchard floor may raise pathogen-related concerns due to potential contact with contaminated water, animal feces, untreated manure, soil, or airborne contaminants (Brandl, 2006). Although there are inherent risks in any fresh produce operation, several pathogens have been reported in apple juice and sweet (nonalcoholic) cider. From 1995 to 2005, 10 of the 21 juice-related outbreaks in the United States were associated with apple juice and sweet cider. The pathogens associated with these outbreaks included *Escherichia coli* O157:H7, *E. coli* O111, *Cryptosporidium parvum*, and one or more unknown pathogens, and many of these juices were unpasteurized before consumption (Vojdani et al., 2008). More recently, *Listeria monocytogenes* has become a pathogen of concern in apple products, partially due to its ability to survive during cold storage and its relative resistance to heat treatments and acidic solutions (Barker and Park, 2001; Mak et al., 2001; Sheng et al., 2017). *Salmonella* species are prolific food pathogens and have appeared in various studies examining food safety processes in apple and other juices. These pathogens, their threat to human health, and their likely contamination sources are outlined in Table 1. Ground-harvested fruit, commonly referred to as “drops,” are also associated with higher levels of patulin, a mycotoxin produced by *Penicillium expansum* and other molds that can be detrimental to human health (Jackson et al., 2003).

European Union regulatory agencies accept that cider can be made from fruit collected from the ground and washed with the understanding that fermentation is an acceptable means of controlling pathogens (Merwin et al., 2008). However, in the United States, those involved with the production of human food and animal feed must comply with the Food Safety Modernization Act (FSMA), which requires that preventive controls are in place for food safety. FSMA has several parts important for food and beverage producers. One section of FSMA, 21 CFR Part 112: *Standards for the*

Table 1. Foodborne pathogens potentially present in apple juice and their potential contamination sources, threats to human health, and infectious doses.

Pathogen	Possible contamination source	Human health risks	Infectious dose	Reference(s)
<i>Escherichia coli</i> O157:H7	Contaminated water Contact with feces	Abdominal cramping	10–100 cells	Armstrong et al., 1996; Gabriel and Nakano, 2009; Jordan et al., 1999; Semanchek and Golden, 1996; U.S. Food and Drug Administration (USFDA), 2012; Wright et al., 2000
		Nausea		
		Vomiting		
		Bloody diarrhea		
		Hemolytic uremic syndrome		
<i>Listeria monocytogenes</i>	Contact with contaminated soil Contact with feces Hard-to-clean areas of the processing facility (i.e., drains)	Gastroenteritis	<1000 cells	Barker and Park, 2001; Gabriel and Nakano, 2009; Tompkin, 2002; USFDA, 2012; Vivant et al., 2013
		Meningitis		
		Septicemia		
		Flu-like symptoms		
		Abortion		
<i>Salmonella</i> sp.	Contaminated water Contact with feces Human transmission	Stillbirth	1 cell	Gabriel and Nakano, 2009; Goverd et al., 1979; USFDA, 2012
		Nausea		
		Vomiting		
		Abdominal cramping		
		Diarrhea		
<i>Cryptosporidium parvum</i>	Contaminated water Human transmission	Fever	10–100 oocysts	Deng and Cliver, 2001; Hanes et al., 2002; Millard et al., 1994; USFDA, 2012
		Headache		
		Diarrhea		
		Dehydration		

Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, or more commonly known as the “Produce Safety Rule,” puts forth mandatory food safety regulations for producers of fresh produce [U.S. Food and Drug Administration (USFDA), 2015a]. In the rule, the term “covered produce” indicates produce that must adhere to the federal standards because it is likely to be consumed raw. Produce not intended for raw consumption is excluded from the definition of “covered produce” but, in this case, processors must be able to show that effective preventive controls have been put in place to reduce the risk of foodborne illness. Apples, including cider apples, can fall into either category. Therefore, apple growers must understand and follow food safety requirements, regardless of market destination, outlined in the FSMA Produce Safety Rule. Farms that generate \$25,000 (adjusted for inflation) or less in produce sales averaged from the previous 3 years are not covered by the rule, as stated in 21 CFR Part 112(a). It is possible for growers to harvest apples for cider production from the ground, but both growers and cidermakers must understand how to best address food safety concerns and ensure that the process adopted for cider manufacture reduces or eliminates pathogen contamination.

This article aims to address the use of ground-harvested apples used for cider production in accordance with the FSMA Produce Safety Rule by examining 1) when apples are considered to be “covered produce,” 2) how processing methods may minimize the risk of foodborne illness when using ground-harvested cider apples for cider production, and 3) how cider apple growers and cider producers may approach compliance and processing exemptions with 21 CFR Part 112 and ensure that their foods are safe.

FSMA Produce Safety Rule

FSMA 21 CFR Part 112 states that all apple cultivars, including cider apples that are only used for cider production, are nonexcluded produce under this rule and must comply with the standards set forth in the regulation. Several categories of produce in 21 CFR Part 112.2 (a), such as potatoes (*Solanum tuberosum*) and corn (*Zea mays*), have been granted

exclusions because of the low likelihood that they would be consumed raw. Apples do not qualify for this exclusion because apples in general are commonly consumed raw, and although cider apple cultivars are unlikely to be consumed raw because of their high tannin levels, dessert and culinary apples are often eaten without further processing. Per 21 CFR Part 112.114, apples that naturally drop due to ripening are considered nonexcluded produce under this rule, although apples that are dropped as part of the harvesting process, such as the shake and sweep method used for hard cider production, may be eligible for a processing exemption. Therefore, apples that have come in contact with the ground outside of normal harvesting methods may be used for human consumption only if there has been adequate processing to reduce food safety concerns.

Like with cider-specific apples, wine grapes (*Vitis vinifera*) and hops (*Humulus lupulus*) used in brewing are unlikely to be consumed raw; wine grapes and hops are not included on the “Rarely Consumed Raw Produce” list and are therefore covered by the rule. However, both wine grapes and hops can be considered “raw produce destined for further processing” and therefore may qualify for a processing exemption if a disclosure statement accompanying the produce states that it was “not processed to adequately reduce the presence of microorganisms of public health significance” as outlined in 21 CFR Part 112.2(b)(2)–(b)(6). In the case of ground-harvested apples, the identified hazards are, at a minimum, patulin and the microbial pathogens addressed in this document.

Growers also may be eligible for qualified exemptions based on total food sales and marketing channels. Figure 1 is a flowchart that details these exclusions and exemptions (USFDA, 2015c).

Processing exemptions for wine, beer, and cider

Wine, beer, and related products are eligible for commercial processing exemptions for the FSMA Produce Safety Rule under 21 CFR Part 112.2 (b). Although the language of the rule does not define what “related products” might be, it is understandable that cider, which undergoes an

alcoholic fermentation process much like wine, would be assumed to fall under this category. However, there are some key differences among wine, beer, and cider production, and additional precautions may be necessary for cider.

Fermentation of grape juice into wine, further referred to as “wine-making,” reduces microbial populations and associated risks through a pH reduction, production of ethanol and carbon dioxide from sugars, creation of an anaerobic environment, and utilization of nutrients by wine yeasts that would otherwise be available for pathogen metabolism (Mørtrø and Daeschel, 2004; Waite and Daeschel, 2007). For beer, microbial populations are greatly reduced by inactivation with heat via wort boiling and pasteurization during the beer-brewing process. Microbial populations in beer are further reduced by increased ethanol concentrations, presence of bittering compounds from hops, low pH (3.4–4.8), and increased carbon dioxide creating an anaerobic environment (Vriesekoop et al., 2012).

Although cider undergoes a process similar to winemaking, the ethanol concentration is much lower than that of wine. Therefore, like beer, cider is often pasteurized to reduce the risk of microbial spoilage that leads to loss of quality. The incorporation of pasteurization into the production of cider, by using pasteurized apple juice or by pasteurizing the cider after fermentation, would be an appropriate method of addressing food safety concerns and reducing pathogenic risks (Mak et al., 2001; Mazzotta, 2001; USFDA, 2004).

Although this document focuses on the FSMA Produce Safety Rule, another notable section of FSMA for food processing is 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food. As stated in 21 CFR Part 117.5(i) producers of alcoholic beverages, including cider, are eligible for exemptions from Subparts C (Hazard Analysis and Risk-Based Preventative Controls) and G (Supply Chain Program) of this regulation (USFDA, 2015b). This is notable, as it demonstrates that alcoholic beverages are considered to be relatively low-risk in terms of food safety compared with other foods and beverages, including juice (USFDA, 2004).

Fig. 1. Flowchart for determination if produce, including apples destined for cider production, is covered under the U.S. Food and Drug Administration (FDA) Produce Safety Rule requirements or eligible for a qualified exemption, adapted from *Standard for Produce Safety: Coverage and Exemptions/Exclusions for 21 Part 112* (U.S. Food and Drug Administration, 2015c).

Cider processing steps to control identified hazards

Both apple growers and cider producers should ensure that microorganisms

of public health concern are adequately reduced by a minimum of a 5-log reduction, the process control standard stated in 21 CFR Part 120 (USFDA, 2004). Apple growers should

be mindful of the growing conditions and handling practices that may cause fluctuations in microbial populations (such as contact with the ground or proximity to livestock areas). Growers also should not commingle ground-harvested fruit with fruit not destined for further processing. Ground-harvested fruit should be labeled as ground-harvested produce destined for further processing and clearly segregated from apples destined for the fresh market. The grower must obtain written assurances from the processor that the fruit will undergo established commercial processing that will “adequately reduce the presence of microorganisms of public health significance,” as stated in 21 CFR Part 112.2(b)(1).

Pathogen populations may be reduced in several ways during the cider-making process. First, clearly damaged and rotten fruit should be culled. Fruit also may be washed to begin to reduce the microbial populations that may be on the surface of the fruit. Washing of produce in potable water with or without sanitizer may result in a small reduction of microorganisms, although washing is unlikely to significantly contribute to a 5-log reduction in microbial populations (Beuchat et al., 1998; Wisniewsky et al., 2000). Sanitizing agents have varying efficacies and may not be as effective on microorganisms that may be harbored within the natural waxy coating, punctures, bruises, stems, and calyxes, so fruit washing should not be relied on as a significant method of pathogen mitigation during cider production (Burnett and Beuchat, 2001).

Pasteurization is a commonly used strategy to reduce microbial loads in juice, and has been well-documented in scientific literature as being effective (Mak et al., 2001; Mazzotta, 2001). Prefermentation pasteurization is an appropriate strategy for decreasing pathogen populations at the start of processing. It is a widespread practice for finished cider to be pasteurized after fermentation to limit incidences of refermentation and spoilage after packaging, and this practice also would be helpful in further reducing pathogen populations.

Juice may be pasteurized using batch or continuous pasteurization to achieve a 5-log pathogen reduction. In batch pasteurization, it is important to monitor the time and temperature

of the juice. A suggested thermal process for juice with a pH range of 3.6 to 4.0 would be 3 s at 71.1 °C (USFDA, 2004). A juice with a pH higher than 4.0 would require a more severe thermal processing due to greater thermotolerance of bacteria as pH approaches neutrality. In a continuous pasteurization process, it is recommended to monitor both the temperature and flow rate so that microbial reduction targets can be met (USFDA, 2004). Small cidermaking operations are unlikely to have a continuous pasteurization unit, unlike larger juice manufacturers.

Cidermakers, however, are likely to pasteurize finished, fermented cider in the package. Small cider productions may use a simple hot water bath for a batch pasteurization process, whereas larger cideries may use steam in a tunnel pasteurizing system. In either case, the goal of pasteurizing the finished cider is to reduce the incidence of spoilage yeast and bacteria, and pathogenic bacteria also can be inactivated during a pasteurization process.

Alternatives to thermal processing to inactivate pathogens of concern include treatment with ultraviolet radiation and high pressure processing, but other processes also may be used (Gabriel and Nakano, 2009; Keyser et al., 2008; USFDA, 2004; Wright et al., 2000). Membrane filtration is also a technique that may reduce microbial populations in juice. Zhao et al. (2015) found that a 5-log reduction in *E. coli* O156:H7 was achievable using 0.8-μm membrane pore size and

a 4.6-log reduction when using a 1.4-μm membrane pore size. For both membrane sizes, *C. parvum* oocysts also were completely removed. Furthermore, removal of suspended solids through the filtration process increased the efficacy of the ultraviolet radiation treatment (Zhao et al., 2015).

Furthermore, unlike grape wine, cider is sometimes made from thermally processed juice concentrate. Although production equipment and methods may vary, thermal concentration of apple juice involves a recommended pretreatment of 80 °C for 30 s to achieve at least a 5-log pathogen reduction (USFDA, 2004).

The addition of preservative agents in cider also may help decrease the populations of many pathogenic bacteria. Sulfur dioxide is commonly added to the juice before and after fermentation. Increased concentrations of molecular sulfur dioxide have been demonstrated to contribute to pathogen inactivation in wine and in sweet (unfermented) cider in some cases (Basaran-Akgul et al., 2009; Waite and Daeschel, 2007). A study observing the effect of sulfur dioxide and dimethyl dicarbonate (DMDC), another wine preservative, found that both antimicrobial agents significantly reduced the survival rate of *E. coli* O157:H7 by up to 5-log (Basaran-Akgul et al., 2009). These effects would be greatest at relatively higher preservative concentrations and low pH levels. At low pH levels, molecular sulfur dioxide, the form most important for antimicrobial effects, is present in higher proportions.

Other preservatives that are commonly used in apple juice production are sodium benzoate and potassium sorbate. The use of 0.1% sodium benzoate, 0.1% potassium sorbate, or a combination of the two has been shown in several studies to effectively reduce levels of *E. coli* O157:H7 in fresh juice (Besser et al., 1993; Ceylan et al., 2004; Fisher and Golden, 1998; Zhao et al., 1993). Studies reveal that 0.1% sodium benzoate and 0.1% potassium sorbate also are more effective at 25 °C than at 4 or 8 °C (Ceylan et al., 2004; Fisher and Golden 1998; Zhao et al., 1993).

Finally, fermentation also may be an effective means of reducing pathogen levels through several mechanisms. Most significantly, fermentation results in the production of ethanol, which has the potential to greatly reduce pathogen levels in cider. A study by Barker and Park (2001) demonstrated the interactive effects of pH, organic acids, and ethanol concentrations on bacterial survival (Table 2). In their model system, *L. monocytogenes* populations were observed to decline, and in some cases not survive, in a 5% vol/vol ethanol solution at pH 3 and 4 compared with the same solution without ethanol. Overall, greater reductions occurred at pH 3 compared with pH 4 regardless of varying organic acid concentrations (Barker and Park, 2001). Reductions in survival rates with the addition of ethanol has also been observed in *E. coli* strains (Jordan et al., 1999; Semancheck and Golden,

Table 2. *Listeria monocytogenes* tolerance to organic acids and/or 5% v/v ethanol at pH 3 and 4 at 37 °C (98.6 °F) showing overall decreased tolerances at the lower pH and decreased tolerances at higher ethanol concentrations (Barker and Park, 2001).

Acid	Survival of <i>L. monocytogenes</i> [mean ± SD (%)] ^a			
	pH 3		pH 4	
	Without ethanol	With 5% v/v ethanol	Without ethanol	With 5% v/v ethanol
None	72 ± 1.2	0.89 ± 0.20	85 ± 22	44 ± 30
Citrate (50 mM) ^b	93 ± 4.6	0.15 ± 0.10	11 ± 5	0.29 ± 0.20
L-Ascorbate (50 mM)	31 ± 8	0.14 ± 0.02	0.76 ± 0.80	6.3 ± 3.4
Propionate (50 mM)	7.7 ± 3.6	0.004 ± 0.004	57 ± 28	7.7 ± 3.7
Acetate (50 mM)	5.7 ± 3.7	0.045 ± 0.038	63 ± 26	13 ± 11
DL-Lactate (50 mM)	0.27 ± 0.25	NS ^c	9.3 ± 3.8	1.0 ± 0.3
DL-Malate (50 mM)	0.015 ± 0.012	NS	0.35 ± 0.11	0.042 ± 0.028
Formate (50 mM)	NS	NS	0.13 ± 0.05	0.002 ± 0.001
Sorbate (10 mM)	0.36 ± 0.12	NS	5.9 ± 2.1	0.056 ± 0.041
Benzoate (10 mM)	NS	NS	0.040 ± 0.015	NS

^aPercent survival is equivalent to the percentage of the colony counts at time zero. Determination of values occurred after 20 min of exposure at pH 3 or after 1 h of exposure at pH 4. The limit of detection was 250 colony-forming units (cfu)/mL (7393.4 cfu/fl oz).

^bValues are equivalent to the concentration of dissociated acids at each respective pH of 3 and 4, and the total concentration of each acid was therefore different for each pH.

^cNo survivors were detected at the time of measurement.

1996). A study evaluating the survival rate of *E. coli* O157:H7 in non-fermented sweet cider and fermenting cider observed that populations in fermenting cider decreased from 6.4 log colony-forming units (cfu)/mL to undetectable levels in 2–3 d compared with non-fermented sweet cider where there was a >3.5 log reduction, but detectable *E. coli* was recovered. *E. coli* O157:H7 populations did not persist in fermenting ciders above an ethanol concentration of 1.94% v/v (Semanchek and Golden, 1996).

A substantial body of scientific evidence suggests that fermentation also is effective for reducing the patulin levels in apple juice (Ough and Corison, 1980; Stinson et al., 1978). Stinson et al. (1978) used three different cider production methods and eight different strains to evaluate the effect of fermentation on patulin concentrations. It was found that fermentation completely destroyed patulin in all but two of the low-alcohol ciders in which the yeast strains used still greatly reduced the patulin concentration (Stinson et al., 1978). Ough and Corison (1980) studied the disappearance of 25 mg·L⁻¹ added patulin in grape juice during storage and fermentation and found that the alcoholic fermentation of juice to produce wine essentially eliminated patulin levels. In addition, pre-fermentation processing steps, such as enzymatic juice clarification with pectic enzymes and sulfur dioxide additions, can reduce patulin levels by removal or destruction, respectively (Bissessur et al., 2001; Ough and Corison, 1980).

Recommendations for apple growers

First, the orchard floor should be evaluated preharvest for potential routes of fecal contamination. Animals and wildlife should be excluded from the area to the extent possible, and surrounding areas should be examined for potential sources of contamination (i.e., a livestock farm uphill). Manure applications should be limited, and the time between application and harvest should be maximized.

During harvesting, fruit should be harvested in a manner that minimizes damage and the amount of time that fruit is on the ground. Workers must be trained to follow appropriate

hygiene procedures, and machinery and equipment, such as picking bins, should be clean so as to not contaminate the orchard site and fruit. Fruit that is rotten or suspected to have been contaminated by animals should not be harvested. Any ground-harvested produce destined for further commercial cider processing must be

clearly labeled and segregated from produce destined for fresh market and be accompanied by documentation that states that the fruit is “not processed to adequately reduce the presence of microorganisms of public health significance,” as stated in 21 CFR Part 112.2(b)(2). Written assurances should be provided to the

Fig. 2. Process flowchart with potential control steps for reduction of pathogens and patulin in juice and cider when using ground-harvested apples. Note that each of these steps may be used individually or in combination with each other to achieve a 5-log reduction in the target microorganism(s). ^zControl step to reduce human pathogen populations. ^yControl step to reduce patulin.

grower from the processor stating that fruit will be processed to “adequately reduce the presence of microorganisms of public health significance.”

Recommendations for cider producers

Culling of any damaged or decayed fruit also should take place before processing. Fruit may be cleaned by brushing off any dirt and debris. Fruit also may be washed with potable water and a sanitizer if applicable.

All fruit processing equipment should be properly cleaned and sanitized. After milling and pressing, juice may be thermally treated by pasteurization or nonthermally treated with ultraviolet radiation, high pressure processing, or another process that has been validated to show that it is effective to reduce pathogen loads. Any experimental data conducted on site that validates the effectiveness of the pasteurization process should be retained as part of the organization's food protection plan. Pasteurization will be a critical control point, and time and temperature treatments for each lot should be recorded as part of the required monitoring activities using established critical limits. Preservatives, in the form of sulfur dioxide, DMDC, sodium benzoate, or potassium sorbate also may be used, and pH can be decreased by addition of malic acid. Once alcoholic fermentation commences, the yeast will compete with other microorganisms for nutrients while increasing the ethanol concentration, further eliminating food sources for pathogens of concern. When the fermentation is complete, preservatives and acid may be added, and the cider may undergo filtration. Cider may be thermally pasteurized or nonthermally treated with ultraviolet radiation or high pressure processing before aseptic packaging, or the cider may be thermally pasteurized in the package. Thermal pasteurization in the package is achieved by either a water bath batch process or a continuous tunnel pasteurizer.

The pathogen reduction processes outlined in this document and in Fig. 2 are strategies to reduce the presence of human pathogens in juice and cider and, when used appropriately, may minimize the risk of exposing consumers to foodborne illnesses. When using ground-harvested apples

for hard cider production, best practices for cider producers include the culling of unsound and rotten apples, washing of apples, pasteurization of the juice before fermentation, the use of sulfites or other preservatives before fermentation, the maintenance of a low pH, alcoholic fermentation, the use of sulfites or other preservatives after fermentation, filtration, and pasteurization after fermentation. However, it should not be assumed that pathogen levels have been sufficiently reduced even when following one or more of these practices. The entire process should be validated by periodically testing for generic *E. coli*, as the presence of this organism indicates insufficient processing steps or unsanitary conditions, and levels of 100 cfu/g or more indicate potential conditions that could allow pathogen survival (National Advisory Committee on Microbiological Criteria for Foods, 2017).

Conclusions

Although apples are clearly defined as covered, nonexcluded produce under 21 CFR Part 112, the concern of using ground-harvested apples to produce alcoholic cider may be minimized by the use of several orchard management and food processing strategies. For growers selling dropped apples, exclusion of potential contaminants and careful documentation of the ground-harvested produce is paramount. For cider producers, incorporation of validated processing steps, if not already in place, will ensure that written assurances can be provided to growers supplying dropped cider apples. Food safety is of utmost importance for any food or beverage producer. As an industry, cider apple growers and cider producers should commit to best practices to prevent illness, comply with regulations, build and maintain trustful relationships with consumers, and sustain economic growth.

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