Using Dropped Apples for Hard Cider Production

Introduction

An issue facing hard cider producers is whether or not 'drops ' or apples that have fallen to the ground before harvest, can be safely used for hard cider production, and if so, under what conditions. This report does not discuss sweet cider, also called fresh cider. In this report the term 'cider' is applied to hard cider which is fermented apple juice.

Analysis

The Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Final Rule (Produce Safety Rule) 21 CFR 112.114 provides that apples that have fallen onto the ground can only be used if they have received commercial processing to adequately reduce the presence of microorganisms. This report does not address the issue of patulin control, a mycotoxin commonly found in fruits including apples. For a review of patulin control, refer to Moake et al. (2005).

Use of Drops in Pasteurized and Unpasteurized Juice vs Hard Cider

Pasteurized apple juice/cider: In general, apples that have come into contact with the ground should only be used for pasteurized juice/cider. Furthermore, the following two steps should be taken when drops are used to make pasteurized juice/cider to ensure product safety:

1) The pasteurization step used should be verified to ensure that a 5 log reduction of the microbe of greatest public health significance has been achieved as required under 21 CFR Part 120. A more severe heat treatment may be necessary since the microbial load is likely to be higher than for harvested fruit (80 FR 223: 74399); and

2) Any pasteurized juice/cider using drops should be tested for *E. coli* and *Listeria* spp. prior to sale, as both of these microbes can survive at the pH of apple juice/cider, and pathogens from these genera can cause serious illness or death in susceptible individuals. If generic forms of these microbes are found, product should not be sold but instead diverted to another use.

Non-pasteurized apple juice/cider: Use of drops should be prohibited since there is no commercial process involved in the production of unpasteurized juice or cider that would adequately reduce the presence of microorganisms.

Hard cider: When pasteurized juice is used, the fermentation process and subsequent aging should be sufficient to reduce the presence of microorganisms of public health significance, presuming that the microbial levels in the pasteurized juice were low following pasteurization and that the juice was not contaminated after the pasteurization process. A pasteurization process must have a sufficient margin of safety and should be designed to inactivate at least a 2 log greater concentration of microbes than the estimated number of the most heat resistant bacteria present in the juice (80 FR 223: 74395. Nov 27 2015; *see also* Ref 88 in Produce Safety Rule references: International Commission on Microbiological Specifications for Foods, 2005)

FDA has added fermentation to their list of examples of commercial processing under §112.2(b)(1) that may be effective for reducing microbial loads, however, the ability of fermentation to inactivate sufficient numbers of pathogenic microbes to ensure product safety will depend upon the initial microbial load of the juice, the resistance of the microbe to the fermentation treatment, pH, and final alcohol content.

Are Cider Apples Exempt Produce?

Produce items destined for further processing that involves one or more steps to inactivate microorganisms of public health significance are subject to less stringent requirements than "covered produce" under the Produce Safety Rule (§ 112.2(b), 80 FR 223: 74391. Nov 27 2015). Covered produce refers to a variety of produce items commonly consumed raw, or raw agricultural commodities (RAC) (Appendix 1). For example in a cider related context, wine grapes would be exempt from the "covered produce" requirements of the Produce Safety Rule since these grapes are delivered to a winery to be made into wine. This exemption would apply even though the farm delivering these grapes would not usually know the specific processes to which the grapes are subjected at the winery and whether the grapes may be transferred to other facilities for fermentation or further processing.

Producers of wine grapes requested an exemption from the covered produce requirements since wine grapes are rarely consumed raw (Comment 73, 21 CFR 112.114 at 74395). FDA denied this categorization, but did note that grapes used for making wine fall within the category of *raw produce destined for further processing*, provided that the farm takes the required steps in accordance with §112.2(b) (Appendix 2) for product segregation and documentation. Cider apples should be treated in a similar manner as wine grapes since they are to be further processed into a fermented beverage.

Conventional Wine and Beermaking and Similar Processes Are Considered to be Adequate to Reduce Microbial Loads

The exemption under §112.2(b) applies to produce that receives commercial processing adequate to reduce pathogen presence, and failure to meet this requirement is a prohibited act under section 301(vv) of the Food Drug & Cosmetic Act (§112.192) for which FDA may take appropriate regulatory action (80 FR 223:74391). Farms that rely on

this exemption must ensure that the produce they are delivering will be adequately processed with a "kill step" to reduce pathogen numbers in order for the farm to be exempt from the "covered produce" requirements of the Produce Safety Rule.

FDA considers the commercial processes for the production of "wine, beer, or similar products to be sufficient to reduce microbial numbers.'' Winemaking and brewing beer adequately reduce the presence of microorganisms of public health significance (Ref. 88 Final Rule, footnote 2 this document) either through a heat treatment (beer) or a high alcohol content (wine) along with the bacterial inhibition that may occur as a result of the fermentation. The issue here is whether or not hard cider is a "similar product" to beer and wine.

The FDA noted that winemaking adequately reduces the presence of microorganisms of public health significance by means other than a cook step; specifically through:

- A reduction in pH,
- The production of alcohol, and
- From the presence of other metabolites associated with the fermentation, in addition to competition of the yeast for nutrients that would thereby reduce the risk of harmful microbial growth) (ICMSF 2005, Ref. 88).

The FDA specifically added processes for making wine, beer or similar products to their list of commercial processing operations in §112.2(b)(1) as ones that are sufficient to "adequately reduce the presence of microorganisms of public health significance" (ICMSF 2005, Ref. 88 and footnote 4). Clearly hard cider is a similar product to wine, cider is made from a produce item that is crushed with its skin and seeds, from which a juice is recovered, that is then fermented using yeast. Therefore the apples used for cider production should be held to the same regulatory requirements as wine grapes.

What is an Adequate Process to Control Microbes of Public Health Significance?

FDA has defined "adequate" to mean that which is needed to accomplish the intended purpose in keeping with good public health practice (21 CFR 112.114 at 74399). The agency further defines ''adequately reduce microorganisms of public health significance'' to mean the presence of such microorganisms to an extent sufficient to prevent illness (21 CFR 112.114 at 74399 Comment 82).

The reduction in pathogen levels from a fermentation treatment must be shown to be sufficient to prevent illness and this is usually determined by either estimating the number of the most resistant pathogens in the food, combined with a safety factor to account for uncertainty in that estimate when the inactivation treatment is designed. Microbial resistance to treatment inactivation will often vary with the food product composition and also for the same food under different circumstances (such as when the

total solids, protein or fat content differs). As noted in a previous guidance document for juice, if the estimated level is 1,000 pathogens per gram of food, and a safety factor of 100 (*i.e.*, 2 logs) is used, the microbial inactivation process must designed to, and then be validated to show, that it reduces the pathogen level by 100,000 (5 log) (FDA 2012, 2009; also cited as Ref. 93 & Ref. 94 in the final rule). Therefore, if the levels of pathogens on fruit destined for cider production are higher than normally anticipated because the harvest or handling practices used could result in a higher microbial load, such as the use of drops, then a sufficient process for pathogen inactivation would have to be more severe (for example, higher heat, longer treatment time, or lower pH).

Does Ethanol Production Kill Deleterious Bacteria?

There are few reports on the effect of ethanol on the susceptibility of microbes to further inactivation in cider (Barker and Park, 2001). These researchers showed that *Listeria monocytogenes*, likely the most risky of the environmental pathogens in an orchard environment, could be killed following exposure to a combination of low pH, the presence of organic acids, plus osmotic stress from the exposure to ethanol (5% v/v). Table 1 from the manuscript, copied here, shows the tolerance of *L. monocytogenes* to various treatments at pH 3 and pH 4 for short incubation periods at 37°C, a temperature higher than what would be used for cider production.

Table 1. Tolerance of stationary phase *L. monocytogenes* (NCTC 7973) to organic acids and/or 5% ethanol (v/v) at pH 3 and 4 at 37°C.

Bacteria Survival[a]				
Acid Type	pH 3		pH 4	
	Without Ethanol	With Ethanol	Without Ethanol	With 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	6.2± 3.4
Propionate, 50 mM	7.7 ± 3.6	0.004 ± 0.004	57 ± 28	7.7± 3.7
Acetate, 5 mM	5.7 ± 3.7	0.045± 0.038	63 ± 26	13± 11
DL-Lactate, 50 mM	0.27 ± 0.25	NS	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, 0 mM	NS, no survivors	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

[a] Survival is expressed as a percentage of the colony counts obtained at time zero. Values were determined after 20 min exposure at pH 3.0 or after 1 hr of exposure at pH 4.0. The data are means ± standard deviation for experiments performed in triplicate. The limit of detection is 250 CFU/ml.

[b] The values are concentration of dissociated acids at pH 3 or 4. The total concentration added was different for each pH.

These data indicate that alcohol and malic acid are both effective at lowering the numbers of *Listeria monocytogenes* in a nutrient medium (TSB-YE) but may not

completely eliminate the bacteria, at least over a short incubation period. At pH 3, 5% ethanol and 50 mM malate, *Listeria monocytogenes* numbers were reduced to below detection limits. At pH 4, 5% ethanol and 50 mM malate, a ~3 log reduction was observed.

Environmental Contamination of Produce

FDA is concerned with various types of environmental contamination and makes a particular note of animals as a source of contamination for fresh produce. In the final rule, the agency revised subpart K of §112.112, requiring these farms to *take all measures reasonably necessary* to identify and not harvest produce commonly consumed raw if it is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including a prohibition on harvesting produce that is visibly contaminated with animal excreta (80 FR 74480). At a minimum, potentially contaminated produce needs to be identified. Once a farmer identifies contaminated produce, or an area where potentially contaminated produce is grown, §112.83(b)(2) requires the farmer to take reasonably necessary measures during the rest of the growing season to reduce the contamination risk, particularly from animals and birds (80 FR 74481).

The agency is concerned with fecal contamination on raw produce and their position is relevant on how to handle "drops". Produce from an area that contains significant amounts of animal excreta that is likely to cross-contaminate the harvested raw produce may not be harvested, and this provision would include drops. The FDA recommends that the impacted area be marked off, by flags for example, to ensure that the particular area is not harvested. The agency set this requirement because rain could wash signs of fecal contamination away making contamination less visible later when the produce is harvested (80 FR 77481). Farmers are required to assess the areas that may have been affected by fecal contamination as necessary during the growing season (§112.83(b)(1)). If signs of possible contamination are found, the farmer is to evaluate whether the covered produce can be harvested safely and take measures reasonably necessary later during harvest season to identify and not harvest covered produce that could be contaminated (21 CFR §112.83(b)(2)).

Farmers are required to visually examine covered produce to be harvested, regardless of the harvest method used. This may be achieved by, for example, visually examining each article of produce and the surrounding areas immediately prior to harvesting the article of produce by hand; or by conducting a visual assessment of the entire growing area and the produce inside the growing area immediately prior to harvest or as soon practicable prior to the start of mechanical or hand harvesting (80 FR at 74486). Similarly under 21 CFR §112.112, a farm that has experienced flooding will also be required to assess the extent of flooding and not harvest covered produce that is reasonably likely to be contaminated by flood water.

FDA was not willing to adopt the position in §112.112 to provide that ''harvesting covered produce that is visibly contaminated with excreta should be avoided

to the *extent practicable*.'' This is because it is well established that animal excreta is a source of pathogens and transmission of pathogens from animal excreta to covered produce and then to humans through consumption is likely. Due to the diversity of covered produce commodities and the agency's desire to allow appropriate flexibility, FDA did not establish commodity specific handling requirements for harvested produce under this particular regulation. Therefore, harvest of visibly contaminated drops would be prohibited for the fresh market, and also for applications where there is not a sufficient kill step.

The Effectiveness of Washing Produce

The FDA decided not to require washing of produce after harvesting since washing and adding disinfectants to wash water cannot be expected to kill all pathogens; washing can also accelerate decomposition of certain fruit and vegetable commodities (Beuchat, 1996 (Ref. 181); Beuchat, 1999 (Ref. 182); Lynch et al. 2009 (Ref. 183). Bacteria may find harborage and protection on plants in hydrophobic areas, stomata, lenticels, punctures, and bruises and where the bacteria are not readily washed off (Seo and Frank, 1999 (Ref. 184); Brackett, 1987 (Ref. 185). As appropriate, farms may choose to wash covered produce, and to add safe and suitable disinfectants to wash water according to label instructions, to reduce the likelihood of contamination and thereby the reduce the risk of cross contamination of surrounding produce with any pathogens that may be introduced into the wash water from a single piece of fruit. Because dropped produce has a greater likelihood of becoming contaminated through contact with the ground, it is likely that any selected washing or sanitization step would be less effective on drops.

Safety of Dropped Covered Produce Such as Apples

FDA considered a total prohibition on farmers from distributing covered produce that drops to the ground before harvest (dropped covered produce) unless it is exempt under §112.2(b) because it was to receive commercial processing adequate to reduce the presence of microorganisms of public health significance (§112.114; 80 FR at 74487). However, the Agency made an exception for dropped produce that is intentionally dropped to the ground as part of the harvesting method; and these items are not considered to be "dropped covered produce". One example is tree nuts that are mechanically harvested in this fashion and for foods where the edible portion is enclosed inside a durable shell. The FDA is not requiring farms to conduct operational assessments or develop farm-specific food safety plans for items such as nuts, although it is encouraging farms to voluntarily identify any specific risks and operational efficiencies appropriate for their circumstances or individual operation as strategies to maintain safe harvest practices.

Farms that raise raw agriculture commodities that are classified as covered produce may take steps to ensure the safety of their dropped covered produce as determined by a farm-specific operational assessment, as long as those steps are

consistent with and do not violate the requirements of this rule, including §112.114. Comments received by the FDA on this regulation questioned the scientific basis for excluding dropped produce from harvest arguing that there it is not certain that pathogens transfer into produce after contact with the ground; also that the likelihood of pathogens being at the exact spot where the produce impacts the ground is remote. However, the FDA concluded that studies of tree fruit (*e.g.*, apples and pears) indicates that dropped and damaged fruit contain coliform bacteria in significantly higher numbers than intact tree fruit (Rioran et al. 1992). In addition, risk assessment models for apple contamination show that dropped apples are more likely to be contaminated with bacteria than tree picked apples (Duffy and Schaffner, 2002 (Ref. 193). Therefore dropped fruit used in the production of apple based beverages, such as cider, are likely to have higher levels of contamination and could result in the production of a microbiogically unsafe product if the cider making process does not involve a kill step that is sufficient to reduce the levels of pathogenic microbes to an acceptable level.

Surface contamination of fruit has resulted in numerous illnesses. Fruits with outer layers that are inedible or typically not consumed have been implicated in illness outbreaks. In 2011–2012, outbreak events have been linked to whole, intact mangoes, papayas, and cantaloupes where peeling knives transferred contamination from the surface to the edible portion. Thus, FDA maintains that provisions of §112.114 should apply generally to covered produce even those fruits with an inedible or rarely consumed outer layer. Their argument is that damage to the skin would allow access of microbes to the interior of the fruit and increased rates of contamination as observed on some types of dropped produce (80 FR 74488). For cider, the apple skin is included during pressing, so any contamination on the surface of the apple would be transferred to the juice or pulp making surface contamination in this particular instance a food safety risk.

Produce that grows off of the ground, such as apples, and drops to the ground before harvest, is considered to be "dropped covered produce" even if the fruit are still attached to the plant when the fruit contacts the ground. This applies to covered produce such as apples that drop to the ground before harvest, or even if the apples are dropped while the harvest is underway. The FDA specifically characterizes apples dropping to the ground before harvesting as dropped covered produce; this is the case even if the farm has already begun harvesting apples within the immediate area and for apples that had unintentionally fallen ''during'' the harvesting of that part of the orchard (80 FR 74488).

Farms may take steps to ensure the safety of their dropped covered produce as determined by a farm-specific operational assessment, as long as those steps are consistent with and do not violate the requirements of the regulation, including §112.114 for items to receive further processing. It may be possible to show that drops harvested following contact with an uncontaminated or minimally contaminated surface could be processed into cider without a "kill step" if the operational assessment showed that these apples did not have higher than normal levels of bacteria.

Conclusions and Recommendations

Dropped apples can be used in hard cider production under certain conditions:

- The drops must be segregated from apples destined for the fresh market. Bins or lots of drops must be clearly labeled for processing use only and not be diverted to the fresh market.

- The harvested apples must otherwise be suitable for use as food and not be decomposed; a reliable assessment should be conducted to show that the level of microbial contamination of the apples used for hard cider production is low, this is particularly important if the juice is not pasteurized prior to fermentation.

- Visual inspection will not be sufficient to determine if drops have been contaminated with harmful microbes. Clearly, apples showing signs of decomposition or the presence of visible contamination are at higher risk of pathogen contamination and should not be used for cider production and be culled out. Individual bin inspection is warranted.

- *Listeria monocytogenes* is a major pathogen of concern with fruits. *L. monocytogenes* is an environmental pathogen and is more heat resistant than other bacterial pathogens such as *E. coli* 0157:H7 or *Salmonella* spp. to heat, sanitizing agents and organic acids. It also survives at the pH of hard cider. Experiments in model systems indicate that fermentation can reduce the level of *Listeria monocytogenes* by 2 log at pH 4, 50 mM malate (no ethanol) and by 3 log at pH 4, 50 mM malate with 5% ethanol following 1 hr incubation at 37^{o}C in a model system. Greater reductions were observed at pH 3, with the potential for 3+ log inactivation within 1 hour (See Table 1). This and other studies indicate that fermentation reduces pathogen levels in cider, however fermentation will only ensure microbial safety if the initial level of microbial contamination is low enough for the fermentation treatment to be effective (Barker and Park, 2001;Bobe et al 2007). Since drops have the potential to have significantly higher levels of microbes than fresh picked apples, a microbial validation study should be conducted prior to the use of drops in cider to ensure that the fermentation process used will be sufficient to inhibit microbial growth. This validation would involve measuring the levels of microbes in the juice and in the cider following fermentation and conducting tests for pathogen presence. If drops are used in cider, in-process and finished product microbiological testing is recommended. Such testing would be a good practice for cider producers to adopt regardless because the ethanol level is significantly lower than for wine.

- Since the microbial load of the drops will likely be higher than picked apples, pasteurizing the juice prior to fermentation is recommended.

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Appendix 1

Food Safety Rule § 112.1 (a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:

(1) Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and

(2) Mixes of intact fruits and vegetables (such as fruit baskets).

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of "farm" as defined in this chapter. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term "covered produce" refers to the harvestable or harvested part of the crop.

Appendix 2

Food Safety Rule § 112.2 What produce is not covered by this part? Produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1),(2), and (3) of this section) under the following conditions:

(1) The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of part 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, **wine, beer or similar products**; and

(2) You must disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is ‘‘not processed to adequately reduce the presence of significance;’’ and

(3) You must either:

(i) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from the customer that performs the commercial processing described in paragraph (b)(1) of this section that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(ii) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in paragraph (b)(1) of this section and that the customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is ‘‘not processed to adequately reduce the presence of microorganisms of public health significance’’; and

(B) Will only sell to another entity that agrees, in writing, it will either:

(*1*) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(*2*) Obtain a similar written assurance from its customer that the produce will receive commercial processing described in paragraph (b)(1) of this section, and that there will be disclosure in documents accompanying the food, in accordance with the practice of the trade, that the food is ‘‘not processed to adequately reduce the presence of microorganisms of public health significance’’; and

(4) You must establish and maintain documentation of your compliance with applicable requirements in paragraphs (b)(2) and (3) in accordance with the requirements of subpart O of this part, including:

(i) Documents containing disclosures required under paragraph (b)(2) of this section; and

(ii) Annual written assurances obtained from customers required under paragraph (b)(3) of this section; and

(5) The requirements of this subpart and subpart Q of this part apply to such produce; and

(6) An entity that provides a written assurance under § 112.2(b)(3)(i) or (ii) must act consistently with the assurance and document its actions taken to satisfy the written assurance.