

# Using Dropped Apples for Cider Production

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# Issue

- Is it safe to use cider apple drops for hard cider production – and if so, under what conditions?



# Cider Apples Are Covered Under The New Produce Safety Rule

- Food Safety Modernization Act applies to Cider
- Cider apples are not exempt – apples are “covered produce” 21 CFR § 112.1(a)
- Wine grapes are “covered produce” - FDA denied wine grapes an exemption from the “covered produce” even though they are rarely consumed raw 21 CFR § 112.114 comment at 80 FR 223:73495
- Wine grapes are “destined for further processing” 21 CFR § 112.2(b)



# FDA's Concern About Drops – What is a Drop?

- The FDA calls out apples.
- Apples are considered to be “dropped covered produce” even if the fruit are still attached to the plant when the apples contact the ground.
- “Drops” include apples that drop to the ground before harvest, even if the harvest is underway, including unintentional drops.



# FDA's Concern About Drops

- FDA was not willing to adopt the position that “harvesting covered produce that is visibly contaminated with excreta should be avoided to the *extent practicable*.”
- 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 *would not establish commodity specific handling requirements* for harvested produce §112.112
- Some dropped produce that is intentionally dropped to the ground as part of the harvesting method is low risk– mechanically harvested tree nuts edible portion is enclosed in a durable shell.



# FDA's Concern About Drops – Farm Practices

- 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 by extension drops (§112.112 80 FR 74481).
- Farmers are required to assess the areas that may have been affected by fecal contamination as needed 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 and take measures reasonably necessary to assist the farm later during harvest to identify and not harvest covered produce that could be contaminated (§112.83(b)(2))



# FDA's Concern About Drops – Processing Exemption

- FDA proposed prohibiting 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 receives commercial processing **adequate** to reduce the presence of microorganisms of public health significance* (§112.114; 80 FR at 74487).



# What is Adequate?

- FDA has defined “adequate” to mean that which is needed to accomplish the intended purpose in keeping with good public health practices (21 CFR 112.114 at 74399)
- A process that “adequately reduces microorganisms of public health significance” leaves pathogenic microbe levels in a food that would not cause illness (21 CFR 112.114 at 74399 Comment 82).



# Comparison of Cider with Wine and Beer

- 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).



# Conventional Wine and Beermaking Have Adequate Processes for Reducing Microbial Load

- FDA considers the commercial processes for “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 either through a **heat treatment** (beer) or a **high alcohol** content (wine) along with the bacterial inhibition that may occur during fermentation.
- The issue here is whether or not hard cider is a “similar product” to beer and wine



# Should Cider Be Considered Similar 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. The apples used for cider production should be held to the same regulatory requirements as for wine grapes
- As long as microbial control processes are *adequate*



# Comparison of Cider and Wine Processing Parameters

- The FDA considers the winemaking process to be “adequate” to reduce the presence of microorganisms of public health significance ***even without a cook step***:
- Reduction in pH,
- Alcohol level,
- Microbial metabolites produced during fermentation,
- Competition of the yeast with microbial pathogens for nutrients (ICMSF 2005, Ref. 88)



# Process Validation Required

- The pathogen levels after a fermentation treatment must not cause illness
- First - estimate the number of the most resistant pathogens in the food,
- Second- 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 and also for the same food under different circumstances (such as when the total solids, protein or fat content is higher).



# Process Validation Required

- FDA Juice Guidance - 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 reduce the pathogen level by 100,000 (5 log) (FDA 2012, 2009; (also cited as Ref. 93 & Ref. 94 in final rule).
- If microbial levels of pathogens on fruit destined for cider production are ***higher than normally anticipated*** due to the harvest or handling practices then a more severe (for example, higher heat or longer treatment time or lower pH) is needed.



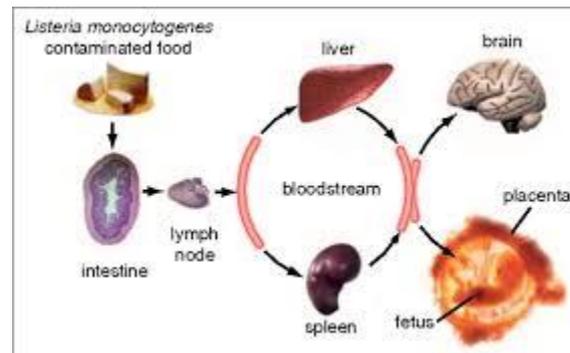
# Wouldn't Hard Cider Be Safe?

- It depends
- Microbial loads are likely to be higher with drops – pasteurization needs to be 2 log greater than the anticipated concentration of microbes 80 FR 223:73495
- FDA added fermentation to list of effective microbial inactivation steps but success depends on initial microbial load and ability of the microbe to survive the fermentation 21 CFR §112.2(b)(1)
- Some ciders may not have a low enough pH or high enough alcohol content to kill *Listeria monocytogenes*



# Does Ethanol Kill (Enough) Bacteria During Cider Production?

- *Listeria monocytogenes*, likely the most risky environmental pathogens in an orchard environment, can be killed by a combination of low pH, organic acids, plus osmotic stress from exposure to ethanol (5% v/v) (Barker and Park, 2001).



**Survival (% of control) Stationary Phase *L. monocytogenes* (NCTC 7973) to Organic Acids and/or 5% Ethanol (v/v) at pH 3 (20 min Exposure) or pH 4 (1 hr Exposure) at 37°C**

Acid	pH 3		pH 4	
	Without EtOH	With EtOH	Without EtOH	With EtOH
None	72	0.9	85	44
Citrate, 50mM	93	0.2	11	0.3
L-Ascorbate, 50 mM	32	0.1	0.8	6
Propionate, 50 mM	8	0.004	57	8
Acetate, 50 mM	6	0.045	63	13
Lactate, 50 mM	0.3	0	9	1
<b>Malate, 50mM</b>	0.02	0	0.4	0.04
Sorbate, 10 mM	0.4	0	6	0.06
Benzoate, 10 mM	0	0	0.04	0

# Cider Fermentation Effectiveness

- Alcohol and malic acid are both effective at reducing *Listeria monocytogenes* in a nutrient medium (TSB-YE) but only to certain levels.
- The maximum reduction at pH 3, 5% ethanol and 50 mM malate were ~3 log at pH 3 and ~2 - 3 log at pH 4 at 37°C.



# Conclusion

- Harvested apples must be suitable for food and with a reliable assessment that the microbial load is relatively low.
- Fermentation can reduce the level of *Listeria monocytogenes* in model systems.
  - Studies must be repeated with real ciders.
- If microbial load of the apples is higher than anticipated, recommend pasteurizing the juice prior to fermentation.
- Validation study to show that **your** fermentation process is sufficient to control pathogens is important.



# Recommendations For Use of Drops - Segregation

- 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.
- Conduct inspection of individual bins.



# Recommendations For Use of Drops – *Listeria* Risk

- *L. monocytogenes* is an environmental pathogen. It is more heat resistant than other bacterial pathogens such as *E. coli* 0157:H7 or *Salmonella* spp. to heat, sanitizing agents and organic acids.
- *L. monocytogenes* survives at the pH of hard cider.
- Fermentation can reduce the level of *Listeria monocytogenes*
- Greater reductions were observed at pH 3 than at pH 4 (See Table 1).
- Fermentation will work only if the initial contamination level is low enough for the fermentation to work (Barker and Park, 2001;Bobe et al 2007).



# Recommendations For Use of Drops – For Unpasteurized Juice

- Drops are likely to have significantly higher levels of microbes than fresh picked apples
  - A microbial validation study should be conducted prior to the use of drops 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. This is 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.
- **Positive release program** – don't sell unless microbial tests show product is pathogen free



# Summary of Recommendations

- Drops should only be used in pasteurized juice or cider
- Pasteurization step should ensure a 5 log reduction 21 CFR Part 120
- A more severe heat treatment may be needed because of higher microbial load in drops 80 FR 223:74399
- Juice from drops should be tested for *Listeria* spp and pathogenic *E. coli* since they may survive at the pH of juice or hard cider and at lower ethanol levels
- Have a positive release program



This slide incorporated recommendation of Marck Seetin, Director of Regulatory and Industry Affairs, US Apple Association

