



# Newsletter

Extension

## Fruit ICM News

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## Recommendations on the Use of Ozone for Pathogen Reduction Purposes in Juice and Cider Guidance for Industry<sup>1</sup>

Source: <http://www.cfsan.fda.gov/~dms/juicgu11.html>

*(Thanks go to Jim Cranney, USAApple, for bringing this article to our attention).*

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. For questions regarding this document, contact Michael E. Kashtock at the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-2022, Fax 301-436-2651, or email [michael.kashtock@fda.hhs.gov](mailto:michael.kashtock@fda.hhs.gov)

This guidance addresses the use of ozone to treat apple juice to meet the pathogen reduction requirements of 21 CFR Part 120 "Hazard Analysis and Critical Control Point (HACCP) Systems" (the juice HACCP regulation) and 21 CFR 101.17(g) "Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens" (the juice labeling regulation).<sup>(2)</sup>

In the fall of 2003, an outbreak of foodborne cryptosporidiosis occurred in Ohio that sickened 148 people. Cryptosporidiosis is a diarrheal illness caused by the protozoan parasite *Cryptosporidium parvum*. This illness can be severe in healthy individuals, and can be life-threatening in immunocompromised persons. Apple cider produced at a local orchard that was treated with ozone for pathogen reduction purposes has been epidemiologically implicated as the responsible food by the U.S. Centers for Disease Control and Prevention. In addition, oocysts of *Cryptosporidium parvum* were present in a container of the implicated apple cider taken from the home of a case patient.

Ozone is a substance that can reduce levels of harmful microorganisms, including pathogenic *E. coli* strains and *Cryptosporidium*, in juice. Ozone is approved as a food additive that may be safely used as an antimicrobial agent in the treatment, storage, and processing of certain foods under the conditions of use prescribed in 21 CFR 173.368.<sup>(3)</sup> Any treatment, including the use of ozone, used to meet the pathogen reduction requirements of the juice HACCP regulation must be carried out as a "process"<sup>(4)</sup> that will produce, at a minimum, a 5-log reduction of the pertinent microorganism (the most resistant organism of public health concern that is likely to occur in the juice.),<sup>(5)</sup> and the treatment process must be validated.<sup>(6)</sup> Similarly, any treatment used to achieve the pathogen reduction requirements of the juice labeling regulation must be a "process" that will produce at least a 5-log reduction in the pertinent microorganism.<sup>(7)</sup> FDA has previously advised that this process should be validated.<sup>(8)</sup>

A processor subject to the juice HACCP regulation would typically address these requirements by identifying a validation study that establishes the efficacy of his process for achieving the 5-log pathogen reduction (21 CFR 120.11 and 120.24), by establishing critical control points (21 CFR 120.8 (b)(2)) and critical limits (21 CFR 120.8 (b)(3)), and by monitoring the process at the critical control points to ensure that the critical limits are met (21 CFR 120.8 (b)(4)). A processor subject to the HACCP regulation is also required to make certain records available to FDA inspectors, including documentation that validates the efficacy of the process for the reduction of the pertinent microorganism, a HACCP plan, and monitoring records (21 CFR 120.12).

A processor subject to the juice labeling regulation is not required to apply HACCP principles to its operations. However, to comply with 21 CFR 101.17(g)(7), the juice must be processed in a manner that will produce, at a minimum, a 5-log reduction in the pertinent microorganism. We would also expect the process to be delivered in a manner that will achieve the required 5-log reduction for the pertinent pathogen, which should include the use of appropriate process controls and monitoring in accord with our "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" regulation in 21 CFR 110.80(b)(2).

As noted, the principles of process and validation apply to all treatments to juice, including the use of ozone as an antimicrobial agent. A validation study can establish the specifics of an ozonation process that are necessary to achieve the 5-log reduction. With ozone, the variables may include the total concentration of ozone introduced into the juice, the flow rate of ozone into the batch tank, the treatment time, the appropriate batch volume, and the degree of agitation of the juice, if any, needed to ensure that the ozone is uniformly dispersed in the juice. Compositional factors, such as the amount and type of juice solids present (e.g., sucrose and organic matter) can vary among different apple juice and cider products and may affect the efficacy of a process. A validation study may also establish how these factors need to be controlled to ensure the efficacy of the ozonation process. However, at this time, FDA is not aware of any published scientific study that establishes conditions for ozonating apple juice to achieve a 5-log pathogen reduction for any pathogen. Therefore, we are advising all processors using (or considering using) ozone for treating apple juice or apple cider to be certain that they comply with the pathogen reduction provisions of the regulation that applies to them, including validation of their process, or implement another means of processing their juice. Processors may consult with a process authority to determine whether a validation study exists that supports their process, and for assistance in establishing processing parameters, e.g., process controls, critical limits, and monitoring procedures. Additional information is also available in our Juice HACCP Hazards and Controls Guidance, First Edition.

**Notes:**

<sup>1</sup> This guidance has been prepared by the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

<sup>2</sup> The juice HACCP regulation, which covers all non-retail juice processors, requires a processor of juice to evaluate its operations using Hazard Analysis Critical Control Point (HACCP) principles and, if necessary, to develop and implement HACCP systems (i.e., a system of preventive control measures based upon HACCP principles) for its operations. The juice labeling regulation, which covers retail processors of juice, requires that any container of juice that has not been treated to achieve a 5-log reduction in the most resistant pathogen bear a warning label informing consumers of the risk associated with consuming untreated juice.

<sup>3</sup> The approval of the use of ozone as an antimicrobial establishes that this use is safe but does not establish the effectiveness of ozone as an antimicrobial under particular conditions of use.

<sup>4</sup> 21 CFR 120.20 sets forth specific requirements for "process controls."

<sup>5</sup> We have recommended in our Juice HACCP Hazards and Controls Guidance, First Edition, that *E. coli* O157:H7 and *Cryptosporidium parvum* be considered when determining the pertinent microorganism for apple juice. Whichever microorganism is most resistant to the process to be used, e.g., heat pasteurization, UV light, is the pertinent microorganism for that process. The guidance is available at: <http://www.cfsan.fda.gov/~dms/juicgu10.html>.

<sup>6</sup> The juice HACCP final rule requires that each processor validate that the HACCP plan is adequate to control hazards that are reasonably likely to occur (21 CFR 120.11(b).) Except for shelf stable juices and juice concentrates, such validation must establish that the HACCP plan is capable of achieving a 5-log reduction in the pertinent microorganism (21 CFR 120.24).

<sup>7</sup> 21 CFR 101.17(g) requires that the juice be "processed."

<sup>8</sup> In the juice labeling final rule, we stated that "consistent with customary scientific practices, the method that produces the 5-log reduction should be validated," (63 FR 37029 at 37042; July 8, 1998) and as such, advised any processor subject to the juice labeling regulation that we would expect its process to be supported by a validation study demonstrating its efficacy against the pertinent pathogen, e.g., *Cryptosporidium parvum*.

## Degree Day Accumulations for Ohio Sites August 4, 2004

Location	Degree Day Accumulations Base 50° F	
	Normal	Actual
Akron-Canton	1740	1679
Cincinnati	2260	2316
Cleveland	1808	1716
Columbus	2200	1985
Dayton	2086	2053
Kingsville	1629	1577

Mansfield	1744	1738
Norwalk	1862	1719
Piketon	2262	2254
Toledo	1852	1718
Wooster	1871	1632
Youngstown	1637	1588

## Pest Phenology

Coming Events	Degree Day Accum. Base 50° F
Oriental fruit moth 2 <sup>nd</sup> flight subsides	1379 - 1771
Apple maggot flight peak	1458 - 1770
San Jose scale 2 <sup>nd</sup> flight peak	1459 - 1805
Spotted tentiform leafminer 3 <sup>rd</sup> flight begins	1532 - 1872

*Thanks to Art Agnello, Cornell University*

## Fruit Observations & Trap Reports

Insect Key	
AM:	apple maggot
CM:	codling moth
ESBM:	eye-spotted budmoth
LAW:	lesser apple worm
LPTB:	lesser peachtree borer
OBLR:	obliquebanded leafroller
OFM:	oriental fruit moth
PTB:	peachtree borer
RBLR:	redbanded leafroller
SJS:	San Jose scale
STLM:	spotted tentiform leafminer
TABM:	tufted apple budmoth
VLR:	variegated leafroller

### Site: Waterman Lab, Columbus

Dr. Celeste Welty, OSU Extension Entomologist

Apple 7/28 to 8/4/04	
Redbanded leafroller	14 up from 9
Spotted	647 down from 1402

tentiform leafminer	
San Jose scale	90 up from 75
Codling moth	7.0 down from 13.2
Lesser appleworm	24 up from 7
Tufted apple budmoth	3 up from 0
Variegated leafroller	2 down from 3
Obliquebanded leafroller	0 same as last wk.
Apple maggot (sum of 3 traps)	8 up from 1

**Site: Holmes, Wayne, and Wayne Counties**

Ron Becker, IPM Program Assistant

<b>Apple: 7/28 to 8/05/04</b>	
Redbanded leafroller	Holmes: 2 down from 6
	Wayne: 4.3 up from 0.3
	Medina: 3.8 up from 0
Spotted tentiform leafminer	Holmes: 240 same as last wk.
	Wayne: 1060 up from 980
	Medina: not available
Oriental fruit moth	Holmes: 0 same as last wk.
	Wayne: 0 down from 1
	Medina: 0 same as last wk.
Codling moth	Holmes: 1.3 down from 2.0
	Wayne: 13.8 up from 12.1
	Medina: 5.1 up from 0.8
Apple maggot (sum of 3 red ball traps, no lure)	Holmes: 4 up from 0
	Wayne: 0 same as last wk
	Medina: 1 up from 0
Lesser appleworm	Wayne: 11 down from 13

<b>Peach: 7/28 to 8/05/04</b>	
Peachtree borer	Holmes: 4 down from 5
	Wayne: 6 up from 4

	Medina: 0 same as last wk. (using mating disruption)
Lesser peachtree borer	Holmes: 1 down from 1
	Wayne: 2 down from 3
	Medina: 0 same as last wk. (using mating disruption)

Ron's comments: Aphid populations decreased, both where pesticides had been applied as well as where they hadn't. Red Haven peaches are now being picked.

**Site: West District; Huron, Ottawa, Richland, and Sandusky Counties**

Lowell Kreager, IPM Scout/Technician

<b>Apple 7/27 to 8/03/04</b>	
Apple maggot (3 trap sum)	0.0 same as last week
Codling moth	2.0 up from 1.1
Lesser appleworm	2.3 down from 3.6
Oriental fruit moth	0.6 down from 2.0
Redbanded leafroller	5.1 up from 4.3
San Jose scale	2.6 up from 1.6
Spotted tentiform leafminer	649 down from 667
<b>Peach 7/27 to 8/03/04</b>	
Lesser peachtree borer	3.0 up from 2.2
Oriental fruit moth	0.7 up from 0.5
Peachtree borer	1.0 up from 0.7
Redbanded leafroller	6.2 up from 4.2

Beneficials include lacewings, lady beetles, and syrphid flies.

**Site: East District; Erie and Lorain Counties**

Jim Mutchler, IPM Scout/Technician

<b>Apple 7/27 to 8/03/04</b>	
Apple maggot (3 trap sum)	3.0 up from 0.2
Codling moth	6.0 up from 3.2
Lesser appleworm	7.6 down from 9.5
Oriental fruit moth	6.4 up from 4.4
Redbanded leafroller	3.7 up from 1.5
San Jose scale	191 down from 218

Spotted tentiform leafminer	285 down from 523
<b>Peach 7/27 to 8/03/04</b>	
Lesser peachtree borer	7.3 up from 3.0
Oriental fruit moth	16.0 up from 3.3
Peachtree borer	24.3 up from 6.0
Redbanded leafroller	1.7 up from 0.5

Beneficials included lacewing eggs and adults, lady beetles, and orange maggots

## Preliminary Monthly Climatological Data for Selected Ohio Locations, July, 2004

Weather Station Location	Monthly Precip	Normal Monthly Precip	Year-to-Date Precip	Normal Year-to-Date Precip	Avg High	Normal High	Avg Low	Normal Low	Mean Temp.	Normal Mean
Akron-Canton	3.12	4.02	27.62	22.84	79.1	82.3	60.8	61.3	69.9	71.8
Cincinnati	6.14	3.75	29.19	26.29	82.3	86.4	64.2	66.1	73.2	76.3
Cleveland	2.88	3.52	23.66	21.99	79.6	81.4	63.2	62.3	71.4	71.9
Columbus	6.46	4.61	32.06	23.43	82.5	85.3	64.8	64.9	73.6	75.1
Dayton	3.25	3.75	28.80	24.34	81.2	84.2	62.9	64.4	72	74.3
Fremont	2.67	3.76	19.64	20.47	81.1	83.9	58.5	61.6	69.8	72.8
Kingsville	7.02	2.90	31.10	19.80	77.5	80.7	61.2	61.2	69.4	71.0
Mansfield	4.48	4.22	30.32	25.49	79.2	81.8	60.5	60.3	69.8	71.1
Norwalk	5.23	4.16	24.94	21.13	81.8	82.4	60.7	61.5	71.3	70.9
Piketon	3.10	4.40	18.44	26.70	83.5	84.6	63.5	62.3	73.5	73.5
Toledo	2.61	2.80	16.23	19.41	82.4	83.4	62.1	62.5	72.2	73.0
Wooster	3.62	4.05	30.86	21.43	81.4	83.6	60.8	59.7	71.1	71.6
Youngstown	4.24	4.10	26.38	22.21	77.8	81.0	59.5	58.7	68.7	69.9

Temperatures in degrees F, Precipitation in inches

*Table Created by Ted W. Gastier, OSU Extension from National Weather Service, OARDC and local data*

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