

Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice

OMB Control No. 0910-0466

SUPPORTING STATEMENT

**Terms of Clearance:** None.

**A. Justification**

1. Circumstances Making the Collection of Information Necessary

FDA regulations in part 120 (21 CFR part 120) mandate the application of hazard analysis and critical control point (HACCP) principles to the processing of fruit and vegetable juices. HACCP is a preventive system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)). Under section 402(a)(4) of the FD&C Act, a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. The Agency also has authority under section 361 of the Public Health Service Act (42 U.S.C. 264) to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State, territory or possession to another, or from outside the United States into this country. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of that Act.

The rationale in establishing a HACCP system of preventive controls is to design and check the process so that the final product is not contaminated - not test for contamination after it may have taken place. Under HACCP, processors of fruit and vegetable juices establish and follow a pre-planned sequence of operations and observations (the HACCP plan) designed to avoid or eliminate one or more specific food hazards, and thereby ensure that their products are safe, wholesome, and not adulterated; in compliance with section 402 of the Act (21 U.S.C. 342). Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety.

We request OMB approval of the following information collection requirements.

**21 CFR 120.6(c), 120.12(a)(1) and (b):  
Sanitation Standard Operating Procedures (SSOP) Monitoring and Correction Records**

Require maintaining records of SSOP sanitation monitoring and correction. The SSOP monitoring and correction records are signed and dated by the individual performing the operation.

**21 CFR 120.7; 120.10(a), 120.12(a)(2), (b) and (c):  
Hazard Analysis**

Require a documented written hazard analysis of food hazards that are reasonably likely to occur for each type of food processed by the processor.

**21 CFR 120.8(b)(7) and 120.12(a)(4)(i) and (b):  
Monitoring Critical Control Points**

Require a recordkeeping system that documents monitoring of the critical control points and other measurements as prescribed in the HACCP plan.

**21 CFR 120.10(c) and 120.12(a)(4)(ii) and (b):  
Corrective Actions**

Set forth requirement that all corrective actions taken in response to a deviation from a critical limit be documented.

**21 CFR 120.11(a)(1)(iv); 120.11(a)(2); and 120.12(a)(5) and (b):  
Verification**

Set forth requirements that records be reviewed for completeness and that the records show that process monitoring instruments are properly calibrated and that end-product or in-process testing is performed in accordance with written procedures. Records are to be documented by the reviewer.

**21 CFR 120.11(b) and (c) and 120.12(a)(5) and (b):  
Validation of the HACCP Plan or Hazard Analysis**

Set forth requirements that every processor record the validation that the HACCP plan is adequate to control food hazards that are likely to occur. When a firm does not have a HACCP plan because the hazard analysis did not reveal hazards likely to occur, sets forth requirements for documenting revalidation of the hazard analysis upon any changes that might affect the original hazard analysis.

**21 CFR 120.14(a)(2), (c) and (d) and 120.12(b):  
Application to Imported Products**

Set forth requirement that importers of fruit or vegetable juices, or their products used as ingredients in beverages, have written procedures to ensure that the food is processed in accordance with these regulations except when the product is obtained from countries that have an active memorandum of understanding with the Food and Drug Administration that the inspection system of the foreign country is equivalent to that of the United States.

**21 CFR 120.24(a)(1) and (2):  
Process Control**

Exempt producers of low acid canned foods and acidified low acid canned foods from the 5-log reduction requirement and associated recordkeeping requirements. Further exempts producers of thermally treated shelf stable and concentrated products from the 5-log reduction requirement and associated recordkeeping requirements provided they document their process in their written hazard analysis.

**21 CFR 120.25, 120.11(a)(1)(vi), and 120.12(a)(5) and (b) :  
Process Verification for Certain Processors**

Set forth requirements for the analysis of the finished product for the presence of microorganisms indicative of insanitation for processors that choose surface treatment of fruit in the production of citrus juice products.

**21 CFR 120.8(a); 120.8(b); 120.12(a)(3), (b) and (c):  
Hazard Analysis Critical Control Point Plan**

Set forth requirements that every processor have a written HACCP plan when a hazard analysis reveals that a food hazard is reasonably likely to occur. Require that plan be documented to signify its acceptance and implementation by the firm.

2. Purpose and Use of the Information Collection

HACCP records are normally reviewed by appropriately trained employees at the end of a production lot or at the end of a day or week of production to verify that control limits have been maintained, or that appropriate corrective actions were taken if the critical limits were not maintained. Such verification activities are essential to ensure that the HACCP system is working as planned. A review of these records during the conduct of periodic plant inspections also permits FDA to determine whether the products have been consistently processed in conformance with appropriate HACCP food safety controls.

Section 120.14 requires that importers of juice take affirmative steps and maintain records that verify that the juice they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 120. These records are also to be made available for review by FDA.

*Description of Respondents:* Respondents to this information collection are processors of fruit and vegetable juices. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

Many of the observations required to document HACCP control point parameters (times, temperatures, acidity, etc.) are amenable to modern data acquisition and processing technology. The Agency encourages the application of this technology for monitoring and recordkeeping operations to minimize the paperwork burden and labor costs, and also to enhance the

organization of records and to facilitate their retrieval. The Agency estimates that about 95 percent (95%) of the responses would be collected electronically.

Companies are free to use whatever forms of information technology may best assist them in developing the proposed recordkeeping. FDA has made this clear in the records provisions of this regulation (§ 120.12 (g)), which states that records maintained as computer files are acceptable when controls are implemented to ensure the integrity of the electronic data and signatures.

#### 4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication of effort in this area. Juice processors that currently use HACCP methods, voluntarily or in accord with State or other federal regulations, are likely to already meet specific hazard avoidance and record keeping requirements, because maintaining records of control point observations is a necessary component of the HACCP method, and not unique to these regulations. Moreover, juice processors that currently process low-acid products under the provisions of 21 CFR part 113 are using HACCP procedures and record keeping to avoid the hazard of Clostridium botulinum toxin that can result from the improper thermal processing of low-acid canned food. These processors are exempted (§§ 120.8 (c) and 120.24(a)(1)) from the HACCP requirements of these regulations that are addressed by the requirements of 21 CFR Parts 113 or 114. Juice processors using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients are also exempted (§ 120.24(a)(2)) from the requirements of these regulations that address hazards controlled by such thermal processes provided that these processors include a copy of the thermal process used to achieve shelf stability or concentration in their written hazard analysis as required by § 120.7. Finally, processors do not need to include in their HACCP plans food hazards that are adequately controlled by a previous processor (§ 120.8(e)).

#### 5. Impact on Small Businesses or Other Small Entities

FDA estimates that a substantial proportion (75%) of juice processors affected by this regulation are small businesses, and has kept their particular needs in mind throughout the development of these regulations. In order to aid small businesses in the implementation of HACCP systems, the proposed effective date for small businesses was extended for one year beyond the effective date of the regulations, and for very small businesses, two years beyond the proposed effective date of the regulations. FDA aids small businesses in complying with the juice HACCP requirements through the agency's Regional Small Business Representatives and through the administrative and scientific staffs within the Agency. FDA has provided a Small Business Guide on the agency's website at <http://www.fda.gov/oc/industry/>, as well as a Juice HACCP Small Entity Compliance Guide at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/ucm072637.htm>.

#### 6. Consequences of Collecting the Information Less Frequently

Data collection occurs daily. Under a HACCP scheme, the frequency of data collection by each processor would occur periodically during daily food processing operations, but that frequency of observation and recording would vary considerably for different processors, depending on the nature and number of the hazards controlled under a HACCP plan. Records "collection" must be continuous once a HACCP plan has been implemented. HACCP has little value if used on a part-time basis, particularly in the context of a regulatory program. In that sense, the "frequency of reporting," that is, the periodic recording and maintaining records of control point observations and related HACCP activities cannot be elective; it must continue from day to day.

The Agency would not "collect" HACCP records or plans as a routine matter. HACCP records would remain on file at each processing facility and would be examined there periodically by the Agency to determine, for example, whether a processor is practicing preventive control measures that are consistent with the hazards presented by fruit and vegetables juices. HACCP plans and records would document that the appropriate HACCP control measures are applied and have been used for all production lots. Finally, the records would establish that the firm is continuously producing safe juices that are in compliance with the provisions of the Act.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of August 30, 2016 (81 FR 59636). FDA received no comments.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Company records describing manufacturing procedures, which may be consulted during FDA plant inspections, and HACCP records that the Agency may copy or take possession of often contain trade secret and commercial confidential information. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), by Section 301(j) of the Act, and by part 20 of the Agency's regulations (21 CFR part 20).

The Agency would attempt to maintain an equitable position consistent with its disclosure regulations and the public interest. Thus, § 120.12(f)(1) states that HACCP plans and records required by part 120 are not available for public disclosure unless they have been previously disclosed, and that HACCP records may be subject to the discretionary disclosure provisions of § 20.81 to the extent that they contain materials that are otherwise publicly available or could not reasonably be expected to cause a competitive hardship if revealed.

## 11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

## 12. Estimates of Annualized Burden Hours and Costs

### 12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden

| 21 CFR Section   | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|--|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| 120.6(c) and 120.12(a)(1) and (b) - Require written monitoring and correction records for Sanitation Standard Operating Procedures (SSOP's).   | 1,875                | 365                             | 684,375              | 0.1 (6 minutes)                  | 68,438      |
| 120.7; 120.10(a); and 120.12(a)(2), (b) and (c)- Require written hazard analysis of food hazards.  | 2,300                | 1.1                             | 2,530                | 20                               | 50,600      |
| 120.8(b)(7) and 120.12(a)(4) (i) and (b)- Require a recordkeeping system that documents monitoring of the critical control points and other measurements as prescribed in the HACCP plan.  | 1,450                | 14,600                          | 21,170,000           | 0.01 (1 minute)                  | 211,700     |
| 120.10(c) and 120.12(a)(4) (ii) and (b)- Require that all corrective actions taken in response to a deviation from a critical limit be documented.   | 1,840                | 12                              | 22,080               | 0.1 (6 minutes)                  | 2,208       |
| 120.11(a)(1)(iv) and (a)(2), and 120.12 (a)(5) and (b)- Require records showing that process monitoring instruments are properly calibrated and that end-product or in-process testing is performed in accordance with written procedures. | 1,840                | 52                              | 95,680               | 0.1 (6 minutes)                  | 9,568       |
| 120.11(b) and (c); and   | 1,840                | 1                               | 1,840                | 4                                | 7,360       |

| 21 CFR Section   | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|--|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| 120.12(a)(5) and (b) - Require that every processor record the validation that the HACCP plan is adequate to control food hazards that are likely to occur.  |                      |                                 |                      |                                  |             |
| 120.11(c) and 120.12(a)(5) and (b) - Require documentation of revalidation of the hazard analysis upon any changes that might affect the original hazard analysis (applies when a firm does not have a HACCP plan because the original hazard analysis did not reveal hazards likely to occur. | 1,840                | 1                               | 1,840                | 4                                | 7,360       |
| 120.14(a)(2), (c), and (d) and 120.12(b) - Require that importers of fruit or vegetable juices, or their products used as ingredients in beverages, have written procedures to ensure that the food is processed in accordance with our regulations in part 120.                               | 308                  | 1                               | 308                  | 4                                | 1,232       |
| 120.8(a), 120.8(b), and 120.12(a)(3), (b) and (c) Require written HACCP plan.  | 1,560                | 1.1                             | 1,716                | 60                               | 102,960     |
| Total  |                      |                                 |                      |                                  | 461,426     |

Table 1 provides our estimate of the total annual recordkeeping burden of our regulations in part 120. We base our estimate of the average burden per recordkeeping on our experience with the application of HACCP principles in food processing. We base our estimate of the number of recordkeepers on our estimate of the total number of juice manufacturing plants affected by the regulations (plants identified in our official establishment inventory plus very small apple juice and very small orange juice manufacturers). These estimates assume that, since the effective date of the final rule establishing 21 CFR part 120, every processor has previously prepared sanitary standard operating procedures under 120.6(a) and 120.12(a)(1) and (b) and a written HACCP plan under 120.8(a) and 120.12(a)(3). These estimates further assume that every processor will maintain the associated monitoring records and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice

processors that, based upon their hazard analysis, determine that they are not required to have a HACCP plan under these regulations.

12b. Annualized Cost Burden Estimate

FDA estimates that the average hourly wage for respondents' workers involved in recordkeeping is equivalent to a GS-5-1 level in the locality pay area of Washington-Baltimore in 2016, approximately \$16.90/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be \$33.80/hour. The overall estimated cost incurred by the respondents is \$15,596,198 (461,426 burden hours x \$33.80/hr = \$15,596,199).

| "Activity and CFR cite" or "Type of Respondent" | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|--------------------|------------------|------------------------|
| Hourly Wage Worker                              | 461,426            | \$33.80          | \$15,596,199           |

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

FDA's review of the retained records would generally occur as part of its routine or for cause establishment inspection activities. FDA estimates that its review of the retained records would take five hours per inspection. FDA estimates the hourly cost for review and evaluation to be \$44.15 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2016. To account for overhead, this cost is increased by 100 percent, making the total cost \$88.30 per hour. Thus, FDA estimates the cost to the Federal Government for the review of records to be \$441.50 per review (\$88.30/hour x 5 hours). FDA estimates that it reviews records for an average of 100 inspections per year. Thus, FDA estimates that the total annual cost to the Federal Government would be \$44,150 (\$441.50 x 100 inspections).

15. Explanation for Program Changes or Adjustments

This collection of information has increased by 1,560 respondents, 1,716 responses, and 102,960 hours. This adjustment in burden is a result of an error that occurred with the last submission of extension. The recordkeeping burden requirement for writing an HACCP plan under sections 120.8(a), 120.8(b), and 120.12(a)(3), (b) and (c) was inadvertently left off of the burden chart in Item 12 in the supporting statement (but was included in the write up in Item 1).

The adjusted total burden requested is now 461,426 recordkeeping hours (358,466 previous recordkeeping hours plus 102,960 new recordkeeping hours).

The previously approved ICR submitted to OMB included eight ICs entered in ROCIS. Upon this submission, we added one IC (left out of the previous submission for extension, in error). With this submission we have also consolidated four of the ICs into two ICs. Therefore, for this submission of extension this ICR now has seven ICs. The information collection activities and the burden associated with each IC, however, remain broken down in this supporting statement and in the table in Item 12.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.