

better anticipate the revenues their raisins will generate.

There are some reporting, recordkeeping and other compliance requirements under the order. The reporting and recordkeeping burdens are necessary for compliance purposes and for developing statistical data for maintenance of the program. The requirements are the same as those applied in past seasons. Thus, this action imposes no additional reporting or recordkeeping burdens on either small or large handlers. The forms require information which is readily available from handler records and which can be provided without data processing equipment or trained statistical staff. The information collection and recordkeeping requirements have been previously approved by the Office of Management and Budget (OMB) under OMB Control No. 0581-0178. As with other similar marketing order programs, reports and forms are periodically studied to reduce or eliminate duplicate information collection burdens by industry and public sector agencies. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

Further, Committee and subcommittee meetings are widely publicized in advance and are held in a location central to the production area. The meetings are open to all industry members, including small business entities, and other interested persons who are encouraged to participate in the deliberations and voice their opinions on topics under discussion.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/fv/moab.html>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

This rule invites comments for a 60-day period on the establishment of final volume regulation percentages for 2001-02 crop NS and OS raisins covered under the order. All comments received within the comment period will be

considered prior to finalization of this rule.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The relevant provisions of this part require that the percentages designated herein for the 2001-02 crop year apply to all NS and OS raisins acquired from the beginning of that crop year; (2) handlers are currently marketing their 2001-02 crop NS and OS raisins and this action should be taken promptly to achieve the intended purpose of making the full trade demands available to handlers; (3) handlers are aware of this action, which was recommended at a public meeting, and need no additional time to comply with these percentages; and (4) this interim final rule provides a 60-day comment period, and all comments timely received will be considered prior to finalization of this rule.

#### **List of Subjects in 7 CFR Part 989**

Grapes, Marketing agreements, Raisins, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 989 is amended to read as follows:

#### **PART 989—RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA**

1. The authority citation for 7 CFR part 989 continues to read as follows:

**Authority:** 7 U.S.C. 601-674.

2. Section 989.255 is added to Subpart—Supplementary Regulations to read as follows:

**Note:** This section will not appear in the annual Code of Federal Regulations.

#### **§ 989.255 Final free and reserve percentages for the 2001-02 crop year.**

The final percentages for standard Natural (sun-dried) Seedless and Other Seedless raisins acquired by handlers during the crop year beginning on August 1, 2001, which shall be free tonnage and reserve tonnage, respectively, are designated as follows:

Varietal type	Free percentage	Reserve percentage
Natural (sun-dried) Seedless .....	63	37
Other Seedless	63	37

Dated: March 27, 2002.

**A.J. Yates,**  
Administrator, Agricultural Marketing Service.

[FR Doc. 02-8141 Filed 4-1-02; 12:11 pm]  
**BILLING CODE 3410-02-P**

## **DEPARTMENT OF AGRICULTURE**

### **Animal and Plant Health Inspection Service**

#### **9 CFR Part 113**

[Docket No. 95-066-2]

#### **Viruses, Serums, and Toxins and Analogous Products; Autogenous Biologics**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are amending the Virus-Serum-Toxin Act regulations for autogenous biologics by reducing the number of test summaries that manufacturers must submit to the Animal and Plant Health Inspection Service. In addition, we are amending the requirement concerning the submission of containers selected from each serial of autogenous biologic that exceeds 50 containers. Manufacturers will hold these containers, and submission is not required unless requested by the Animal and Plant Health Inspection Service. These actions will result in savings in time and resources for autogenous biologics manufacturers and the Animal and Plant Health Inspection Service without a significant reduction in regulatory oversight.

**EFFECTIVE DATE:** May 3, 2002.

**FOR FURTHER INFORMATION CONTACT:** Dr. Albert P. Morgan, Chief Staff Officer, Operational Support Section, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1231; (301) 734-8245.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

The regulations in 9 CFR part 113 (referred to below as the regulations) contain standard requirements for the preparation of veterinary biological products. Section 113.113 of the regulations sets forth the requirements for autogenous biologics. Autogenous biologics are prepared from cultures of microorganisms that are isolated from sick or dead animals from a particular flock or herd. The cultures are used to produce an autogenous veterinary

biological product that is administered to other animals of the originating flock or herd to prevent them from being infected by the same disease.

Autogenous biologics may also be used in adjacent and nonadjacent herds under certain conditions, if approved by the Administrator of the Animal and Plant Health Inspection Service (APHIS).

Autogenous biologics are intended for use in isolated cases of diseases in animals when licensed products are not available or such products are unable to protect the vaccinated animals (e.g., the strain of microorganism in the licensed product differs from the strain associated with the disease outbreak). Autogenous biologics can also be used to respond to emergency outbreaks of animal diseases when the immediate need for the product is such that it precludes the usual route of vaccine development.

Given the special circumstances pertaining to the preparation and use of autogenous biologics, special testing and serial release reporting requirements have been applied. In § 113.113, paragraph (c)(1)(ii) allows first serials or subserials of an autogenous biologic that are satisfactory after the third day of observation of the purity test cultures and safety test animals to be released for shipment to the customer while the purity and safety tests are continued through the required period. Paragraph (c)(1)(iii) of § 113.113 provides that such serials must be immediately recalled if evidence of contamination occurs in the purity test or if any of the test animals used to demonstrate product safety become sick or die during the observation period. However, because autogenous biological products can be shipped prior to the completion of testing, the products, in most cases, have been used in animals prior to the completion of testing. In addition, § 113.113(c)(1)(iv) requires autogenous biologics manufacturers to submit to APHIS the test summaries of the first serial or subserial within 4 days of the completion of the purity and safety tests. The test summaries must be submitted to APHIS in accordance with § 116.7 of 9 CFR part 116, "Records and Reports." (Section 116.7, in short, provides the requirements for maintenance of detailed records of all tests conducted on each serial and subserial and the preparation and submission of summaries of such tests using APHIS Form 2008 or an acceptable equivalent form prior to release of the serial or subserial.

In 1993, the last year for which full data are available, veterinary biologics manufacturers submitted approximately

11,400 autogenous biologics first serial test summaries to APHIS for processing, and the number of reports has increased in succeeding years. However, we believe that the requirement to submit test summaries from the first serial or subserial of an autogenous biologic within 4 days of completion of purity and safety tests for serials that may have already been used in animals is unnecessary. We believe that these reports can be submitted on a quarterly basis without reducing our regulatory oversight.

On March 8, 2000, we published in the **Federal Register** (65 FR 12151–12153, Docket No. 95–066–1) a proposal to amend the regulations for autogenous biologics. We proposed to reduce the number of test summaries that autogenous biologics manufacturers must submit to APHIS, and to amend the requirement concerning the submission to APHIS of containers selected from each serial of autogenous biologic that exceeds 50 containers. Manufacturers would hold these containers and submit them to APHIS when requested.

We solicited comments concerning our proposal for 60 days ending May 8, 2000. We received four comments by that date. They were from two veterinary biologics manufacturers and two trade associations representing veterinary biologics manufacturers. We carefully considered these before reaching a final decision concerning our proposal. Two comments were received after the close of the comment period. However, the issues they raised were not materially different from those contained in the timely comments.

Of the four comments that were received by the May 8, 2000, close of the comment period, three expressed support for the changes set forth in the proposed rule, but suggested additional changes or requested that we clarify points related to reserve samples. Two commenters observed that first serials or subserials of autogenous biologics are frequently not shipped due to contamination, an unsatisfactory test, or for other reasons. Both suggested wording for § 113.3(b)(8) that would make the requirement to select samples for submitting to APHIS applicable to the "first serial or subserial of autogenous biologic eligible for shipment." We agree with the commenters regarding the need to make it clear that this provision is only applicable to the first serials or subserials of autogenous biologics eligible to be shipped and, therefore, in the final rule each reference to first serial or subserial is changed to "first

serial or subserial of autogenous biologic eligible for shipment."

With regard to reserve samples, one commenter questioned whether the proposed wording of § 113.3(b)(8) requires 10 containers of autogenous biologic selected for submission upon request by APHIS to be held in reserve until 6 months beyond the expiration date. It appears that our use of the term "reserve" in § 113.3(b)(8) in the proposed rule could be interpreted as requiring that 10 containers be held in reserve until 6 months beyond the expiration date. Because it was not our intent to change the requirements of § 113.3(e) for reserve samples, the term "reserve" has been deleted in this final rule. The second sentence of § 113.3(b)(8) now reads: "For first serials or subserials of autogenous biologic eligible for shipment with more than 50 containers, 10 samples from each serial or subserial must be selected and held for submission to the Animal and Plant Health Inspection Service upon request in accordance with paragraph (e)(4) of this section."

In addition, one of the commenters suggested that § 113.3(b)(8) be modified to provide that samples not selected for testing by APHIS could be restocked by the manufacturer and become eligible for distribution. We believe that the disposition of samples not selected for testing by APHIS is beyond the scope of the proposed rule; thus, we are making no changes in this final rule as a result of that comment.

One commenter was opposed to the provisions set forth in the proposed rule. The commenter stated that the proposed changes would result in a weakening of the regulatory oversight that APHIS is expected to provide concerning the regulation of autogenous biologics. We believe that the changes to the regulations contained in the proposed rule and this final rule will not weaken our regulatory oversight. The regulations that we are amending have required samples to be submitted to APHIS when selected and test summaries to be submitted within 4 days of test completion, whereas under this final rule, manufacturers will be required to hold samples for submission when requested by APHIS and to submit test summaries on a quarterly basis. Confirmatory testing of autogenous samples will remain at current levels, and quarterly test summaries will be monitored to ensure that tests are completed satisfactorily and accurately reported. Therefore, we have made no change to this final rule in response to this comment.

The same commenter stated that the proposed special testing and serial

release reporting requirements pertaining to the preparation and use of autogenous biologics would result in preferential treatment for firms producing autogenous biologics that is unavailable to firms that do not prepare those products. The commenter requested that the special testing and serial release reporting requirements proposed for autogenous biologics be extended to all products and all manufacturers. We agree that the regulations, as amended by this final rule, will provide for different treatment of autogenous biologics under certain special circumstances, but we would like to emphasize that this different treatment only applies to the first serial or subserial of autogenous biologic that is produced from an isolate. Thereafter, the preparation of autogenous biologics is subject to the same treatment as other biologics; each serial or subserial of autogenous biologic other than the first serial or subserial prepared from that same isolate must be prepared in accordance with the applicable general requirements for bacterial or viral products specified in the regulations, and any serial or subserial found unsatisfactory by any prescribed test shall not be released. In addition, the preparation of autogenous biologics is not restricted and that all manufacturers may, at their option, choose to produce autogenous biologics and take advantage of the special testing and serial release reporting requirements applicable to first serials or subserials of autogenous biologics. We have made no change in this final rule in response to that comment.

Some comments regarding the regulation of autogenous biologics were not specific to the provisions in the proposal. These comments stated that the preparation and distribution of such products are not in keeping with the intent for autogenous biologics as cited in the preamble to the proposed rule. These commenters were concerned that autogenous biologics may be more widely distributed than should be allowed; may not be adequately evaluated for extraneous agents; may not be effective under certain circumstances; and may not be evaluated adequately for safety. We have also made no changes in this final rule in response to those comments.

One change that had been proposed was an address correction in § 113.113(a)(2). This change does not appear in this final rule because the address in that section is correct.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposal as a final

rule, with the changes discussed in this document.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This rule amends the Virus-Serum-Toxin Act regulations for autogenous biologics by reducing the number of test summaries that manufacturers of autogenous veterinary biologics must submit to APHIS. This rule also amends the requirements concerning the submission of containers selected from each serial of autogenous biologic that exceeds 50 containers to provide that manufacturers will hold these containers and not submit them unless requested by APHIS. These actions will result in savings in time and resources for autogenous biologics manufacturers and APHIS without a significant reduction in regulatory oversight.

The entities expected to be affected by this rule are veterinary biologics establishments that produce autogenous biologics. There are currently approximately 135 veterinary biologics establishments that may fit that category. According to the Small Business Administration's criteria, many of those establishments would be classified as small entities.

This rule provides that 10 samples must be selected for submission when requested by APHIS from each serial or subserial of autogenous biologics, with the exception of first serials or subserials, that exceeds 50 containers, and that test summaries of autogenous biologics must be submitted on a quarterly basis as summary reports by the 21st day of January, April, July, and October, or more often as required by the Administrator. These changes to the regulations are not expected to have any adverse economic effects on firms and may provide a benefit, since the amount of time and resources required to complete reports and/or package samples for submission to APHIS should be reduced.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

#### **Executive Order 12372**

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires

intergovernmental consultation with State and local officials (see 7 CFR part 3015, subpart V).

#### **Executive Order 12988**

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. The Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

#### **Paperwork Reduction Act**

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). It actually reduces the information collection without a disruption to program services.

#### **List of Subjects in 9 CFR Part 113**

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR Part 113 as follows:

#### **PART 113—STANDARD REQUIREMENTS**

1. The authority citation for part 113 continues to read as follows:

**Authority:** 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

2. In § 113.3, paragraph (b)(8) is revised to read as follows:

##### **§ 113.3 Sampling of biological products.**

\* \* \* \* \*

(b) \* \* \*

(8) *Autogenous biologics:* With the exception of the first serial or subserial, 10 samples must be selected and submitted to the Animal and Plant Health Inspection Service from each serial or subserial of an autogenous biologic eligible to be shipped that consists of more than 50 containers. For first serials or subserials eligible for shipment consisting of more than 50 containers, 10 samples from each serial or subserial must be selected and held for submission to the Animal and Plant Health Inspection Service upon request in accordance with paragraph (e)(4) of this section. For serials or subserials of autogenous biologic with 50 or fewer containers, no samples, other than those required by paragraph (e) of this section, are required.

\* \* \* \* \*

3. In § 113.113, the introductory text of paragraph (a)(2) and paragraph (c)(1)(iv) are revised to read as follows:

**§ 113.113 Autogenous biologics.**

\* \* \* \* \*

(a) \* \* \*

(2) Under normal circumstances, microorganisms from one herd must not be used to prepare an autogenous biologic for another herd. The Administrator, however, may authorize preparation of an autogenous biologic for use in herds adjacent to the herd of origin, when adjacent herds are considered to be at risk. To request authorization to prepare a product for use in herds adjacent to the herd of origin, the establishment seeking authorization must submit to the Administrator (in c/o the Director, Center for Veterinary Biologics, Inspection and Compliance, 510 South 17th Street, Suite 104, Ames, IA 50010-8197) the following information. (If any of the data are unavailable, the applicant for authorization should indicate that such data are unavailable and why.)

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

(iv) Test summaries must be submitted to the Administrator (in c/o the Director, Center for Veterinary Biologics, Inspection and Compliance, 510 South 17th Street, Suite 104, Ames, IA 50010-8197) on a quarterly basis by the 21st day of January, April, July, and October or more often as required by the Administrator.

\* \* \* \* \*

Done in Washington, DC, this 28th day of March, 2002.

**W. Ron DeHaven,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 02-8058 Filed 4-2-02; 8:45 am]

BILLING CODE 3410-34-P

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**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 39**

[Docket No. 2001-CE-42-AD; Amendment 39-12695; AD 2002-07-01]

**RIN 2120-AA64**

**Airworthiness Directives; Cessna Aircraft Company P206, TP206, TU206, U206, 207, T207, 210, P210, and T210 Series Airplanes**

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD) that applies to certain Cessna Aircraft Company (Cessna) P206, TP206, TU206, U206, 207, T207, 210, P210, and T210 series airplanes. This AD requires you to visually inspect certain horizontal stabilizer attachment reinforcement brackets for the existence of seam welds and replace any reinforcement bracket found without seam welds. This AD authorizes the pilot to check the logbooks to determine whether one of the affected horizontal stabilizer attachment reinforcement brackets is installed. This AD is the result of a report that certain parts were manufactured without seam welds. The actions specified by this AD are intended to detect and replace structurally deficient horizontal stabilizer attachment brackets. Continued use of such brackets could result in structural failure of the horizontal stabilizer with reduced or loss of control of the airplane.

**DATES:** This AD becomes effective on May 13, 2002.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulations as of May 13, 2002.

**ADDRESSES:** You may get the service information referenced in this AD from Cessna Aircraft Company, Product Support, P.O. Box 7706, Wichita, Kansas 67277; telephone: (316) 517-5800; facsimile: (316) 942-9006. You may view this information at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2001-CE-42-AD, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Al Phillips, Aerospace Engineer, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946-4116; facsimile: (316) 946-4407.

**SUPPLEMENTARY INFORMATION:**

**Discussion**

*What events have caused this AD?*

Cessna notified FAA of a defect in the manufacturing of the horizontal stabilizer attachment reinforcement brackets. Cessna manufactured reinforcement brackets without seam welds on certain Cessna Model 206H and T206H airplanes. AD 2001-09-06, Amendment 39-12211 (66 FR 21278, April 30, 2001), addresses these

airplanes. The seam welds help provide the required structural integrity for the horizontal stabilizer attachment bracket.

Since the issuance of AD 2001-09-06, Cessna determined that certain Model P206, TP206, TU206, U206, 207, T207, 210, P210, and T210 series airplanes may have had horizontal stabilizer attachment reinforcement brackets (part number 1232624-1) without seam welds installed as replacement parts. Cessna shipped these brackets from February 27, 1998, through March 17, 2000.

*What is the potential impact if FAA took no action?*

This condition, if not corrected, could result in structural failure of the horizontal stabilizer with reduced or loss of control of the airplane.

*Has FAA taken any action to this point?*

We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain Cessna P206, TP206, TU206, U206, 207, T207, 210, P210, and T210 series airplanes. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on December 17, 2001 (66 FR 64925). The NPRM proposed to require you to visually inspect the right and left horizontal stabilizer attachment reinforcement brackets for the existence of seam welds along the lower inboard and outboard wall/flange. The NPRM also proposed to require you to remove and replace any horizontal stabilizer bracket found without seam welds.

*Was the public invited to comment?*

The FAA encouraged interested persons to participate in the making of this amendment. We did not receive any comments on the proposed rule or on our determination of the cost to the public.

**FAA's Determination**

*What is FAA's final determination on this issue?*

After careful review of all available information related to the subject presented above, we have determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. We have determined that these minor corrections:

- Provide the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.