except for the written SE prevention plan, offsite. You must be able to retrieve and provide the records at your place of business within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(e) *Official review of records*. You must have all records required by this part available for official review and copying at reasonable times.

(f) *Public disclosure of records*. Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

§ 118.11 Registration requirements for shell egg producers covered by the requirements of this part.

(a) Shell egg producers covered under § 118.1(a) are required to register their farms with FDA within 30 days of becoming an egg producer or, if already an egg producer, by each farm's applicable compliance date.

(b) Shell egg producers may register their farms by any of the following means:

(1) *Electronic registration*. To register electronically, you must register at *http://www.access.fda.gov*, which will be available for registration 24 hours a day, 7 days a week beginning May 10, 2010. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes.

(i) An individual authorized by the owner or operator of a farm, such as an agent in charge, may also register a farm electronically.

(ii) FDA strongly encourages electronic registration for the benefit of both FDA and the registrant.

(iii) Once you complete your electronic registration, FDA will automatically provide you with an electronic confirmation of registration and a permanent registration number.

(iv) You will be considered registered once FDA electronically transmits your confirmation and registration number.

(2) *Registration by mail or by fax*. If, for example, you do not have reasonable access to the Internet through any of the methods described in paragraph (b)(1) of this section, an individual authorized by the owner or operator of a farm, such as an agent in charge, may register by mail or fax.

(i) You must register using FDA Form No. 3733. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration, 5600 Fishers Lane (HFS–681), Rockville, MD 20857, or by requesting the form by phone at 1–800–216–7331 or 301–575–0156.

(ii) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(2)(i) of this section or fax it to the number on the form.

(iii) If any required information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the form was received by the agency (i.e., by mail or fax).

(iv) FDA will enter complete and legible mailed and faxed registration submissions into its registration system, along with CD–ROM submissions, as soon as practicable, in the order FDA receives them.

(v) FDA will then mail to the address or fax to the fax number on the registration form a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the agency (i.e., by mail or fax).

(vi) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration. If any information you previously submitted that was correct at the time of submission subsequently changes, you must update your facility's registration within 60 calendar days.

(vii) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(3) *Registration by CD–ROM for multiple submissions*. If, for example, you do not have reasonable access to the Internet through any of the methods

provided under paragraph (b)(1) of this section, you may register by CD–ROM.

(i) Registrants submitting their registrations in CD–ROM format must use ISO 9660 (CD–R or CD–RW) data format.

(ii) These files must be submitted on a portable document format (PDF) rendition of the registration form (FDA Form No. 3733) and be accompanied by one signed copy of the certification statement that appears on the registration form.

(iii) Each submission on the CD–ROM must contain the same preferred mailing address in the appropriate block on FDA Form No. 3733.

(iv) A CD–ROM may contain registrations for as many facilities as needed up to the CD–ROM's capacity.

(v) The registration on the CD–ROM for each separate facility must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(vi) You must mail the CD–ROM to the U.S. Food and Drug Administration, 5600 Fishers Lane (HFS–681), Rockville, MD 20857.

(vii) If FDA receives a CD–ROM that does not comply with these specifications, it will return the CD–ROM to the submitter unprocessed.

(viii) FDA will enter CD–ROM submissions that comply with these specifications into its registration system, along with the complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(ix) For each facility on the CD–ROM, FDA will mail to the preferred mailing address a copy of the registration(s) as entered, confirmation of registration, and each facility's assigned registration number.

(x) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration. If any information you previously submitted that was correct at the time of submission subsequently changes, you must update your facility's registration within 60 calendar days.

(xi) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(c) No registration fee is required.

(d) You must submit all registration information in the English language. All information must be submitted using the Latin (Roman) alphabet.

(e) Each registrant must submit the following information through one of the methods described in paragraph (b) of this section:

(1) The name, full address, and phone number of the farm; and

(2) The average or usual number of layers of each house and number of poultry houses on the farm.

(3) A statement in which the shell egg producer certifies that the information submitted is true and accurate. If the individual submitting the form is not the shell egg producer in charge of the farm, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit registration, and identifies by name, address, and telephone number, the individual who authorized submission of the registration. Each registration must include the name of the individual registering the farm submitting the registration, and the individual's signature (for paper and CD–ROM options).

(f) Registered egg producers must submit an update to a registration within 60-calendar days of any change to any of the information previously submitted by any of the means as provided in § 118.11(b).

(g) Registered egg producers must notify FDA within 120 days of ceasing egg production by completing sections 1b, 1c, and 2 of Form 3733. This notification is not required if you are a seasonal egg producer or you temporarily cease operation due to labor disputes, fire, natural disasters, or other temporary conditions.

[74 FR 33095, July 9, 2009, as amended at 75 FR 18751, Apr. 13, 2010]

§ 118.12 Enforcement and compliance.

(a) *Authority*. This part is established under authority of the Public Health Service Act (the PHS Act). Under the FFDCA, the Food and Drug Administration (FDA) can enforce the food adulteration provisions under 21 U.S.C. 331 through 334 and 342. Under the PHS