



FDA Visit to Pack House Procedure for Residue Testing

1. Follow your visitor standard operating procedure & policy on regulatory visits.
 - a. At arrival, FDA investigator signs in; presents his/her ID.
 - b. Investigator may present "Notice of Inspection" (FDA Form 482).
 - c. Inquire about the nature of the visit.
 - d. The FDA investigator should be joined by a designated knowledgeable person, such as the plant, production or quality manager. The firm's representative should accompany the investigator throughout the visit and ask questions if in doubt about the investigator's procedures.
 - e. Be professional and respectful.

2. Notify NYAS: Kaari Stannard, John Cushing, Matt Wells, and Chelsea Van Acker Gowan.

3. Document the entire visit.
 - a. Arrival and departure time, date.
 - b. Nature of visit (random pesticide sampling, random pathogen testing, other)
 - c. Product tested
 - i. Lot / Size / Pack / variety / grower / Block
 - ii. Details of sampling techniques used by FDA.
 1. Number of apples / gloves & other PPE used to gather sample. How many different locations sampled / type of container used to hold samples.
 - iii. Ask FDA investigator how long will test results take.
 - d. Capture who the investigator has spoken to, where visited in facility, and topics of discussion.

Business decisions:

4. 3rd Party Residue Test:
 - a. Take a duplicate sample (one that mirrors what the FDA has taken) and submit sample for residue testing. EMA labs – general 2+ days with overnight delivery.
5. Perform a traceback & identify all product at risk.
 - a. Place all product on hold associated with the FDA samples –
6. Decide how long to hold product:
 - a. POSITIVE FDA TEST (pesticide over US MRL) – Could result in a recall and/or fines. Test could take up to 2 weeks for results or longer.
 - b. NEGATIVE FDA TEST – No consequences.
 - c. POSITIVE 3rd party Residue TEST - Recall product, test results usually back in 2 days.
 - d. NEGATIVE 3rd party Residue TEST – Usually back within 2 days, you can ship, however your FDA results still may be pending and if they come back positive that could be a recall.